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Sponsor

Novartis Pharmaceuticals

Generic Drug Name

WVT078 and WHG626

Trial Indication(s)

Relapsed and/or refractory multiple myeloma

Protocol Number

CWVT078A12101

Protocol Title

A Phase I, open-label, multicenter, study of WVT078 in subjects with relapsed and/or refractory multiple myeloma

Clinical Trial Phase

Phase 1

Phase of Drug Development

Phase I

Study Start/End Dates

Study Start Date: December 05, 2019 (Actual)
Primary Completion Date: December 02, 2024 (Actual)

Study Completion Date: December 02, 2024 (Actual)

Reason for Termination (If applicable)

Enrollment to WVT078 single agent of this study was halted on 18-Oct-2021 and enrollment to WVT078 + WHG626 combination arm of this study was halted on 15-Mar-2023; in both cases, enrolment halt was due to business reasons and the decision was not based on any safety or tolerability concerns.

Due to the enrollment halt of both arms, the dose expansion part of the study was not initiated.

Study Design/Methodology

This was a first-in-human, phase I, multicenter, open-label study to determine the safety and tolerability of WVT078 alone and in combination with WHG626 in participants with multiple myeloma (MM). Eligible participants had received two or more standard of care (SoC) lines of therapy including an immunomodulatory drug (IMiD) (e.g. lenalidomide or pomalidomide), a proteasome inhibitor (e.g. bortezomib, carfilzomib), and an anti-CD38 agent (e.g. daratumumab) (if available). Participants were required to be relapsed and/or refractory to, or intolerant of, each regimen, with documented disease progression according to International Myeloma Working Group (IMWG) criteria, and not eligible for other regimens known to provide clinical benefit, as determined by the investigator.

This study consisted of a dose-escalation part with two treatment arms (Arms A and B), each followed by an expansion part.

During dose escalation, participants with relapsed and/or refractory MM (r/r MM) were treated with single agent WVT078 (Arm A) or WVT078 in combination with WHG626 (Arm B) until the maximum tolerated dose/recommended dose (MTD/RD) of each was reached. The dose escalation was guided by an adaptive Bayesian logistic regression model (BLRM) for Arm A and Arm B following the escalation with overdose control (EWOC) principle.

Once the MTD(s)/RD(s) was determined in each escalation part, additional participants were to be enrolled in the expansion part in order to further characterize the pharmacokinetics (PK), pharmacodynamics (PD), and safety profile of the study

drugs, and to assess the preliminary anti-tumor activity of WVT078 as a single agent and in combination with WHG626. However, the dose expansion was not explored following the enrollment halts to both treatment arms for business reasons.

Centers

12 centers in 8 countries: United States(3), Germany(2), Spain(2), Israel(1), Japan(1), Italy(1), Australia(1), Norway(1)

Objectives:

The primary objective of the trial was to characterize the safety, tolerability, and determine recommended dose regimen(s) of single agent WVT078, and WVT078 in combination with WHG626 in subjects with relapsed and/or refractory multiple myeloma.

The secondary objectives were:

- Assess preliminary anti-MM response of single agent WVT078, and WVT078 in combination with WHG626 in subjects with relapsed and/or refractory MM.
- Characterize pharmacokinetics and immunogenicity of single agent WVT078, WVT078 in combination with WHG626, and the pharmacokinetics of GWQ573 (the active metabolite of WHG626), in subjects with relapsed and/or refractory MM. Assess the immunogenicity of WVT078.

Test Product (s), Dose(s), and Mode(s) of Administration

For this study, the term “investigational drug” and “study treatment” refer to WVT078 and/or WHG626.

- WVT078 was administered as a 2-hour intravenous (i.v.) infusion, once per week (QW) on a continuous schedule.
- WHG626 was administered orally as capsules, following a 2 days on/5 days off weekly dosing schedule.

In Arm A (single agent arm), WVT078 was administered at dose levels ranging from 3 mcg/kg to 250 mcg/kg.

In Arm B (combination arm), WVT078 was administered at dose levels ranging from 12 mcg/kg to 48 mcg/kg, and WHG626 was given at either 2 mg or 4 mg.

The study treatment period began on Cycle 1 Day 1, with each cycle lasting 28 days.

Study treatment continued until a patient experienced unacceptable toxicity, progressive disease as per IMWG or treatment was discontinued at the discretion of the investigator or the patient.

Statistical Methods

Primary endpoint:

The primary endpoints defined to evaluate the safety of WVT078 and WVT078 in combination with WHG626 were incidence and severity of adverse events (AEs) and serious adverse events (SAEs), including changes in laboratory values, vital signs, ECGs and cytokine release syndrome (CRS)/immune-mediated reactions. Tolerability was evaluated in terms of dose interruptions, dose reductions, and dose discontinuations. Identification of recommended dose would be evaluated by incidence of dose limiting toxicities (DLTs) in Cycle 1.

Secondary endpoints:

The secondary efficacy endpoints used to assess the preliminary anti-tumor activity of WVT078 or WVT078 in combination with WHG626 are Best overall response (BOR), Progression free survival (PFS), and Duration of response (DOR) as per International Multiple Myeloma Working Group (IMWG) criteria.

The secondary PK endpoints used to characterize pharmacokinetics (PK) and immunogenicity of WVT078 or WVT078 in combination with WHG626 are serum concentration of WVT078, plasma concentration of WHG626 and GWQ573, and PK parameters (e.g., AUC, Cmax, Cmin, Tmax, T1/2 (half-life)), concentration vs. time profiles, and presence and/or titre of anti-WVT078 antibodies.

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Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:

- Subjects with relapsed and/or refractory MM who have received two or more standard of care regimens including an IMID, proteasome inhibitor, and an anti-CD38 agent (if available)

Exclusion Criteria:

- Plasma cell leukemia and other plasmacytoid disorders, other than MM
- Prior use of BCMAxCD3 bispecific therapies
- Use of systemic chronic steroid therapy (>or= 10mg/day prednisone or equivalent) or any immunosuppressive therapy within 7 days of first dose of study treatment
- Malignant disease other than being treated on this study
- Active known or suspected autoimmune disease
- Impaired cardiac function or clinically significant cardiac disease
- Treatment with cytotoxic or small molecule antineoplastics or any experimental therapy within 14 days or 5 half-lives whichever is shorter
- Active central nervous system involvement by malignancy or presence of symptomatic CNS metasteses

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Participant Flow Table

Overall Study

	WVT078 3mcg/kg	WVT078 6mcg/kg	WVT078 12mcg/kg	WVT078 24mcg/kg	WVT078 48mcg/kg	WVT078 64mcg/kg	WVT078 96mcg/kg	WVT078 192mcg/kg	WVT078 250mcg/kg	WVT078 12mcg/kg + WHG62 6 2mg	WVT078 24mcg/kg + WHG62 6 2mg	WVT078 48mcg/kg + WHG62 6 2mg	WVT078 48mcg/kg + WHG62 6 4mg	Total
Arm/Group Description	Arm A: WVT078 3 mcg/kg QW	Arm A: WVT078 6 mcg/kg QW	Arm A: WVT078 12 mcg/kg QW	Arm A: WVT078 24 mcg/kg QW	Arm A: WVT078 48 mcg/kg QW	Arm A: WVT078 64 mcg/kg QW	Arm A: WVT078 96 mcg/kg QW	Arm A: WVT078 192 mcg/kg QW	Arm A: WVT078 250 mcg/kg QW	Arm B: WVT078 12 mcg/kg QW in combination with WHG62 6 2 mg 2 days on/5 days off	Arm B: WVT078 24 mcg/kg QW in combination with WHG62 6 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG62 6 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG62 6 4 mg 2 days on/5 days off	
Started	1	2	2	2	4	1	3	14	4	5	4	10	4	56
Completed	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Not Completed*	1	2	2	2	4	1	3	14	4	5	4	10	4	56
Adverse Event	0	0	0	0	0	0	0	1	1	0	0	2	0	4
Physician Decision	0	0	0	0	0	0	0	1	0	0	0	0	0	1
Progressive Disease	1	2	2	2	4	1	3	12	3	5	4	6	2	47

Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0	0	0	1	2	3
Guardian Decision	0	0	0	0	0	0	0	0	0	0	0	1	0	1

* Not completed refers to treatment discontinuation. The reasons for discontinuation are listed below.

Baseline Characteristics

	WVT078 3mcg/kg	**WVT078 6mcg/kg**	**WVT078 12mcg/kg**	**WVT078 24mcg/kg**	**WVT078 48mcg/kg**	**WVT078 64mcg/kg**	**WVT078 96mcg/kg**	**WVT078 192mcg/kg**	**WVT078 250mcg/kg**	**WVT078 12mcg/kg + WHG62 6 2mg**	**WVT078 24mcg/kg + WHG62 6 2mg**	**WVT078 48mcg/kg + WHG62 6 2mg**	**WVT078 48mcg/kg + WHG62 6 4mg**	**Total**
Arm/Group Description	Arm A: WVT078 3 mcg/kg QW	Arm A: WVT078 6 mcg/kg QW	Arm A: WVT078 12 mcg/kg QW	Arm A: WVT078 24 mcg/kg QW	Arm A: WVT078 48 mcg/kg QW	Arm A: WVT078 64 mcg/kg QW	Arm A: WVT078 96 mcg/kg QW	Arm A: WVT078 192 mcg/kg QW	Arm A: WVT078 250 mcg/kg QW	Arm B: WVT078 12 mcg/kg QW in combination with WHG62 6 2 mg 2 days on/5 days off	Arm B: WVT078 24 mcg/kg QW in combination with WHG62 6 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG62 6 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG62 6 4 mg 2 days on/5 days off	
Number of Participants [units: participants]	1	2	2	2	4	1	3	14	4	5	4	10	4	56

Baseline Analysis Population Description														
Age Continuous (units: years) Analysis Population Type: Participants Median (Full Range)														
	66.0 (66 to 66)	64.5 (63 to 66)	65.5 (63 to 68)	60.0 (54 to 66)	60.5 (55 to 71)	64.0 (64 to 64)	57.0 (50 to 64)	65.5 (50 to 75)	68.5 (58 to 71)	67.0 (64 to 76)	56.5 (49 to 64)	66.0 (54 to 76)	59.0 (55 to 69)	NA[]
Age, Customized (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)														
18 - <65 years	0	1	1	1	3	1	3	7	1	1	4	5	3	31
65 - <85 years	1	1	1	1	1	0	0	7	3	4	0	5	1	25
Sex: Female, Male (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)														
Female	1	1	0	1	2	1	0	6	2	3	1	3	3	24
Male	0	1	2	1	2	0	3	8	2	2	3	7	1	32
Race/Ethnicity, Customized (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)														
Asian	1	0	0	0	2	0	0	0	0	0	0	0	0	3

Black or African American	0	0	0	1	0	0	0	0	0	0	0	1	0	2
White	0	2	2	1	2	1	3	14	4	5	4	9	4	51

Primary Outcome Result(s)

Number of participants with Dose-Limiting Toxicities (DLTs) in the first cycle

Description	A DLT is defined as an adverse event or abnormal laboratory value of Common Terminology Criteria for Adverse Events (CTCAE) grade ≥ 3 where the relationship to single agent WVT078 or WVT078 in combination with WHG626 cannot be ruled out, and is not clearly related solely to disease progression or inter-current illness, that occurs within the first cycle of study treatment (28 days) and meets the criteria defined in the study protocol. Other clinically significant toxicities may be considered to be DLTs, even if not CTCAE grade 3 or higher.
Time Frame	First cycle of treatment (28 days)
Analysis Population Description	Dose-Determining Set (DDS) including all participants in the dose escalation who met the minimum exposure criterion defined in the protocol and had sufficient safety evaluations or had experienced a DLT during the first cycle.

	WVT078 3mcg/kg	**WVT078 6mcg/kg**	**WVT078 12mcg/kg**	**WVT078 24mcg/kg**	**WVT078 48mcg/kg**	**WVT078 64mcg/kg**	**WVT078 96mcg/kg**	**WVT078 192mcg/kg**	**WVT078 250mcg/kg**	**WVT078 12mcg/kg + WHG626 2mg**	**WVT078 24mcg/kg + WHG626 2mg**	**WVT078 48mcg/kg + WHG626 2mg**	**WVT078 48mcg/kg + WHG626 4mg**
Arm/Group Description	Arm A: WVT078 3 mcg/kg QW	Arm A: WVT078 6 mcg/kg QW	Arm A: WVT078 12 mcg/kg QW	Arm A: WVT078 24 mcg/kg QW	Arm A: WVT078 48 mcg/kg QW	Arm A: WVT078 64 mcg/kg QW	Arm A: WVT078 96 mcg/kg QW	Arm A: WVT078 192 mcg/kg QW	Arm A: WVT078 250 mcg/kg QW	Arm B: WVT078 12 mcg/kg QW in combination with WHG62	Arm B: WVT078 24 mcg/kg QW in combination with WHG62	Arm B: WVT078 48 mcg/kg QW in combination with WHG62	Arm B: WVT078 48 mcg/kg QW in combination with WHG62

										6 2 mg 2 days on/5 days off	6 2 mg 2 days on/5 days off	6 2 mg 2 days on/5 days off	6 4 mg 2 days on/5 days off
Number of Participants Analyzed [units: participants]	1	2	1	2	4	1	3	12	3	3	4	9	4
Number of participants with Dose-Limiting Toxicities (DLTs) in the first cycle (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
At least one DLT	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (100%)	0 (%)	1 (8.33%)	0 (%)	0 (%)	1 (25%)	2 (22.22%)	2 (50%)
Cytokine release syndrome	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (8.33%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Pneumonia	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (100%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (25%)	0 (%)	0 (%)
Aspartate aminotransferase increased	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	2 (22.22%)	0 (%)
Thrombocytopenia	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (11.11%)	1 (25%)
Alanine aminotransf	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (11.11%)	0 (%)

erase increased													
Lipase increased	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (25%)
Neutropenia	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (25%)	0 (%)	0 (%)
Pneumococcal sepsis	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (25%)
Tumor pain	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (25%)

Number of participants with AEs and SAEs during the on-treatment period

Description	Number of participants with AEs (any adverse events regardless of seriousness) and serious adverse events (SAEs), including changes in physical exams, electrocardiograms and laboratory results qualifying and reported as AEs. AE grades to characterize the severity of the AEs were based on the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0. For CTCAE v5.0, Grade 1 = mild; Grade 2 = moderate; Grade 3 = severe; Grade 4 = life-threatening; Grade 5 = death. The on-treatment period is defined from the day of first administration of any study treatment up to 30 days after the date of the last actual administration of any study drug.
Time Frame	Up to 45 months (median 2.4 months) in Arm A, and up to 29.1 months (median 3.8 months) in Arm B.
Analysis Population Description	All participants who received at least one dose of study treatment.

	WVT078 3mcg/kg	**WVT078 6mcg/kg**	**WVT078 12mcg/kg**	**WVT078 24mcg/kg**	**WVT078 48mcg/kg**	**WVT078 64mcg/kg**	**WVT078 96mcg/kg**	**WVT078 192mcg/kg**	**WVT078 250mcg/kg**	**WVT078 12mcg/kg + WHG62 6 2mg**	**WVT078 24mcg/kg + WHG62 6 2mg**	**WVT078 48mcg/kg + WHG62 6 2mg**	**WVT078 48mcg/kg + WHG62 6 4mg**
Arm/Group Description	Arm A: WVT078 3 mcg/kg QW	Arm A: WVT078 6 mcg/kg QW	Arm A: WVT078 12 mcg/kg QW	Arm A: WVT078 24 mcg/kg QW	Arm A: WVT078 48 mcg/kg QW	Arm A: WVT078 64 mcg/kg QW	Arm A: WVT078 96 mcg/kg QW	Arm A: WVT078 192 mcg/kg QW	Arm A: WVT078 250 mcg/kg QW	Arm B: WVT078 12 mcg/kg QW in combination with	Arm B: WVT078 24 mcg/kg QW in combination with	Arm B: WVT078 48 mcg/kg QW in combination with	Arm B: WVT078 48 mcg/kg QW in combination with

										WHG62 6 2 mg 2 days on/5 days off	WHG62 6 2 mg 2 days on/5 days off	WHG62 6 2 mg 2 days on/5 days off	WHG62 6 4 mg 2 days on/5 days off
Number of Participants Analyzed [units: participants]	1	2	2	2	4	1	3	14	4	5	4	10	4
Number of participants with AEs and SAEs during the on-treatment period (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
AEs	1 (100%)	2 (100%)	2 (100%)	2 (100%)	4 (100%)	1 (100%)	3 (100%)	14 (100%)	4 (100%)	5 (100%)	4 (100%)	10 (100%)	4 (100%)
Treatment-related AEs	1 (100%)	0 (%)	1 (50%)	2 (100%)	4 (100%)	1 (100%)	3 (100%)	13 (92.86%)	4 (100%)	4 (80%)	4 (100%)	9 (90%)	4 (100%)
AEs with grade>= 3	0 (%)	0 (%)	2 (100%)	1 (50%)	3 (75%)	1 (100%)	3 (100%)	13 (92.86%)	4 (100%)	5 (100%)	4 (100%)	8 (80%)	4 (100%)

Treatment-related AEs with grade>=3	0 (%)	0 (%)	1 (50%)	0 (%)	2 (50%)	1 (100%)	2 (66.67%)	9 (64.29%)	4 (100%)	2 (40%)	3 (75%)	7 (70%)	4 (100%)
SAEs	0 (%)	0 (%)	2 (100%)	2 (100%)	0 (%)	1 (100%)	0 (%)	10 (71.43%)	4 (100%)	2 (40%)	4 (100%)	7 (70%)	4 (100%)
Treatment-related SAEs	0 (%)	0 (%)	0 (%)	1 (50%)	0 (%)	1 (100%)	0 (%)	8 (57.14%)	2 (50%)	1 (20%)	4 (100%)	5 (50%)	1 (25%)
Fatal SAEs	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (10%)	0 (%)
Treatment-related fatal SAEs	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Number of Participants with dose reductions, interruptions, and discontinuations of WVT078

Description	Number of participants who experienced at least one dose reduction or interruption of WVT078, as well as those who permanently discontinued treatment. Permanent discontinuations are recorded in two categories: those due to adverse events (AEs) and those due to any reason, including AEs. Dose adjustments were permitted for participants who did not tolerate the protocol-specified dosing schedule.
Time Frame	Up to 44 months (median 1.4 months) in Arm A, and up to 28.1 months (median 2.8 months) in Arm B.
Analysis Population Description	All participants who received at least one dose of WVT078.

	WVT078 3mcg/kg	**WVT078 6mcg/kg**	**WVT078 12mcg/kg**	**WVT078 24mcg/kg**	**WVT078 48mcg/kg**	**WVT078 64mcg/kg**	**WVT078 96mcg/kg**	**WVT078 192mcg/kg**	**WVT078 250mcg/kg**	**WVT078 12mcg/kg +**	**WVT078 24mcg/kg +**	**WVT078 48mcg/kg +**	**WVT078 48mcg/kg +**

										WHG626 2mg	**WHG626 2mg**	**WHG626 2mg**	**WHG626 4mg**
Arm/Group Description	Arm A: WVT078 3 mcg/kg QW	Arm A: WVT078 6 mcg/kg QW	Arm A: WVT078 12 mcg/kg QW	Arm A: WVT078 24 mcg/kg QW	Arm A: WVT078 48 mcg/kg QW	Arm A: WVT078 64 mcg/kg QW	Arm A: WVT078 96 mcg/kg QW	Arm A: WVT078 192 mcg/kg QW	Arm A: WVT078 250 mcg/kg QW	Arm B: WVT078 12 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 24 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 4 mg 2 days on/5 days off
Number of Participants Analyzed [units: participants]	1	2	2	2	4	1	3	14	4	5	4	10	4
Number of Participants with dose reductions, interruptions, and discontinuations of WVT078 (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
At least one dose reduction	0 (%)	0 (%)	0 (%)	1 (50%)	1 (25%)	1 (100%)	1 (33.33%)	6 (42.86%)	3 (75%)	1 (20%)	0 (%)	5 (50%)	4 (100%)

or interruption													
At least one dose reduction	0 (%)	0 (%)	0 (%)	0 (%)	1 (25%)	1 (100%)	0 (%)	2 (14.29%)	2 (50%)	0 (%)	0 (%)	3 (30%)	2 (50%)
At least one dose interruption	0 (%)	0 (%)	0 (%)	1 (50%)	1 (25%)	0 (%)	1 (33.33%)	5 (35.71%)	3 (75%)	1 (20%)	0 (%)	5 (50%)	4 (100%)
Permanent discontinuation due to AE	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (7.14%)	1 (25%)	0 (%)	0 (%)	2 (20%)	0 (%)
Permanent discontinuation due to any reason	1 (100%)	2 (100%)	2 (100%)	2 (100%)	4 (100%)	1 (100%)	3 (100%)	14 (100%)	4 (100%)	5 (100%)	4 (100%)	10 (100%)	4 (100%)

Number of Participants with dose reductions, interruptions, and discontinuations of WHG626

Description	Number of participants who experienced at least one dose reduction or interruption of WHG626, as well as those who permanently discontinued treatment. Permanent discontinuations are recorded in two categories: those due to adverse events (AEs) and those due to any reason, including AEs. Dose adjustments were permitted for participants who did not tolerate the protocol-specified dosing schedule.
Time Frame	Up to 28.1 months (median 2.8 months)
Analysis Population Description	All participants who received at least one dose of WHG626.

	WVT078 12mcg/kg + WHG626 2mg	**WVT078 24mcg/kg + WHG626 2mg**	**WVT078 48mcg/kg + WHG626 2mg**	**WVT078 48mcg/kg + WHG626 4mg**
Arm/Group Description	Arm B: WVT078 12 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 24 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 4 mg 2 days on/5 days off

Number of Participants Analyzed [units: participants]	5	4	10	4
Number of Participants with dose reductions, interruptions, and discontinuations of WHG626 (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
At least one dose reduction or interruption	2 (40%)	1 (25%)	6 (60%)	4 (100%)
At least one dose reduction	0 (%)	0 (%)	1 (10%)	4 (100%)
At least one dose interruption	2 (40%)	1 (25%)	6 (60%)	4 (100%)
Permanent discontinuation due to AE	0 (%)	0 (%)	3 (30%)	0 (%)
Permanent discontinuation due to any reason	5 (100%)	4 (100%)	10 (100%)	4 (100%)

Secondary Outcome Result(s)

Best Overall Response (BOR) per IMWG criteria

Description	BOR is defined as the best response recorded from the start of the study treatment until disease progression/recurrence, based on local investigator assessment per International Multiple Myeloma Working Group (IMWG) criteria.
Time Frame	Up to 44 months (median 1.4 months) in Arm A, and up to 28.1 months (median 2.8 months) in Arm B.
Analysis Population Description	All participants who received at least one dose of study treatment.

WVT078 3mcg/kg	**WVT078 6mcg/kg**	**WVT078 12mcg/kg**	**WVT078 24mcg/kg**	**WVT078 48mcg/kg**	**WVT078 64mcg/kg**	**WVT078 96mcg/kg**	**WVT078 192mcg/kg**	**WVT078 250mcg/kg**	**WVT078 12mcg/kg +**	**WVT078 24mcg/kg +**	**WVT078 48mcg/kg +**	**WVT078 48mcg/kg +**

										WHG626 2mg	WHG626 2mg	WHG626 2mg	WHG626 4mg
Arm/Group Description	Arm A: WVT078 3 mcg/kg QW	Arm A: WVT078 6 mcg/kg QW	Arm A: WVT078 12 mcg/kg QW	Arm A: WVT078 24 mcg/kg QW	Arm A: WVT078 48 mcg/kg QW	Arm A: WVT078 64 mcg/kg QW	Arm A: WVT078 96 mcg/kg QW	Arm A: WVT078 192 mcg/kg QW	Arm A: WVT078 250 mcg/kg QW	Arm B: WVT078 12 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 24 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 4 mg 2 days on/5 days off
Number of Participants Analyzed [units: participants]	1	2	2	2	4	1	3	14	4	5	4	10	4
Best Overall Response (BOR) per IMWG criteria (units: participants)	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**	**Count of Participants (Percentage)**
Stringent Complete Respon	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (33.33%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (10%)	1 (25%)

se (sCR)													
Complete Response (CR)	0 (%)	0 (%)	0 (%)	0 (%)	1 (25%)	0 (%)	0 (%)	0 (%)	2 (50%)	0 (%)	0 (%)	2 (20%)	1 (25%)
Very Good Partial Response (VGPR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	2 (14.29%)	0 (%)	0 (%)	0 (%)	1 (10%)	1 (25%)
Partial Response (PR)	0 (%)	0 (%)	0 (%)	0 (%)	1 (25%)	1 (100%)	0 (%)	0 (%)	1 (25%)	1 (20%)	0 (%)	3 (30%)	0 (%)
Minimal Response (MR)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (25%)	1 (10%)	0 (%)
Stable Disease (SD)	0 (%)	0 (%)	0 (%)	1 (50%)	1 (25%)	0 (%)	0 (%)	5 (35.71%)	0 (%)	0 (%)	1 (25%)	0 (%)	1 (25%)
Progressive Disease (PD)	1 (100%)	1 (50%)	0 (%)	1 (50%)	1 (25%)	0 (%)	1 (33.33%)	5 (35.71%)	1 (25%)	1 (20%)	1 (25%)	1 (10%)	0 (%)
Unknown (UNK)	0 (%)	1 (50%)	2 (100%)	0 (%)	0 (%)	0 (%)	1 (33.33%)	2 (14.29%)	0 (%)	3 (60%)	1 (25%)	1 (10%)	0 (%)

Duration of Response (DOR) per IMWG criteria

Description	DOR applies only to participants with a BOR of sCR, CR, VGPR or PR as assessed by IMWG. It is defined as the time from the date of first documented disease response (sCR, CR, VGPR or PR) to the date of first documented progression as assessed by IMWG or death due to multiple myeloma. If a participants did not have an event, duration of overall response was censored at the date of the last adequate assessment.
Time Frame	Up to approximately 47 months (median 4.4 months) in Arm A, and up to approximately 32 months (median 5.8 months) in Arm B.

Analysis Population Description: All participants who received at least one dose of study treatment and achieved sCR, CR, VGPR or PR per IMWG criteria.

	WVT078 3mcg/kg	WVT078 6mcg/kg	WVT078 12mcg/kg	WVT078 24mcg/kg	WVT078 48mcg/kg	WVT078 64mcg/kg	WVT078 96mcg/kg	WVT078 192mcg/kg	WVT078 250mcg/kg	WVT078 12mcg/kg + WHG626 2mg	WVT078 24mcg/kg + WHG626 2mg	WVT078 48mcg/kg + WHG626 2mg	WVT078 48mcg/kg + WHG626 4mg
Arm/Group Description	Arm A: WVT078 3 mcg/kg QW	Arm A: WVT078 6 mcg/kg QW	Arm A: WVT078 12 mcg/kg QW	Arm A: WVT078 24 mcg/kg QW	Arm A: WVT078 48 mcg/kg QW	Arm A: WVT078 64 mcg/kg QW	Arm A: WVT078 96 mcg/kg QW	Arm A: WVT078 192 mcg/kg QW	Arm A: WVT078 250 mcg/kg QW	Arm B: WVT078 12 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 24 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 4 mg 2 days on/5 days off
Number of Participants Analyzed [units: participants]	0	0	0	0	2	1	1	2	3	1	0	7	3
Duration of Response (DOR) per IMWG criteria (units: months)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**

26.1 (7.0 to 45.1)	7.4 (7.4 to 7.4)	12.7 (12.7 to 12.7)	11.2 (10.4 to 12.1)	20.5 (4.1 to 39.4)	15.2 (15.2 to 15.2)		6.9 (1.0 to 32.8)	20.4 (9.2 to 21.2)

Progression-Free Survival (PFS) per IMWG criteria

Description	PFS was based on local review of tumor assessments, using IMWG criteria. PFS is defined as the time from the date of start of treatment to the date of the first documented progression as assessed using IMWG Criteria or death due to any cause. In case a participant did not have progression or death prior to data cutoff, PFS was censored at the date of the last adequate assessment on or prior to the earliest censoring event. PFS was analyzed using the Kaplan-Meier method in groups with at least 10 patients treated.
Time Frame	Up to approximately 47 months (median 4.4 months) in Arm A, and up to approximately 32 months (median 5.8 months) in Arm B.
Analysis Population Description	All participants who received at least one dose of study treatment.

	WVT078 3mcg/kg	**WVT078 6mcg/kg**	**WVT078 12mcg/kg**	**WVT078 24mcg/kg**	**WVT078 48mcg/kg**	**WVT078 64mcg/kg**	**WVT078 96mcg/kg**	**WVT078 192mcg/kg**	**WVT078 250mcg/kg**	**WVT078 12mcg/kg + WHG62 6 2mg**	**WVT078 24mcg/kg + WHG62 6 2mg**	**WVT078 48mcg/kg + WHG62 6 2mg**	**WVT078 48mcg/kg + WHG62 6 4mg**
Arm/Group Description	Arm A: WVT078 3 mcg/kg QW	Arm A: WVT078 6 mcg/kg QW	Arm A: WVT078 12 mcg/kg QW	Arm A: WVT078 24 mcg/kg QW	Arm A: WVT078 48 mcg/kg QW	Arm A: WVT078 64 mcg/kg QW	Arm A: WVT078 96 mcg/kg QW	Arm A: WVT078 192 mcg/kg QW	Arm A: WVT078 250 mcg/kg QW	Arm B: WVT078 12 mcg/kg QW in combination with WHG62 6 2 mg 2 days on/5 days off	Arm B: WVT078 24 mcg/kg QW in combination with WHG62 6 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG62 6 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG62 6 4 mg 2 days on/5 days off
Number of Participants	1	2	2	2	4	1	3	14	4	5	4	10	4

Analyzed [units: participants]													
Progression-Free Survival (PFS) per IMWG criteria (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**
	NA (NA to NA)[1]	NA (NA to NA)[1]	NA (NA to NA)[1]	NA (NA to NA)[1]	NA (NA to NA)[1]	NA (NA to NA)[1]	NA (NA to NA)[1]	2.1 (1.0 to 2.4)	NA (NA to NA)[1]	NA (NA to NA)[1]	NA (NA to NA)[1]	7.9 (1.1 to NA)[2]	NA (NA to NA)[1]

[1] Not estimable because n<10.
[2] Not estimable due to insufficient number of participants with events.

Maximum observed serum concentration (Cmax) of WVT078

Description	Pharmacokinetic (PK) parameters were calculated based on WVT078 serum concentrations by using non-compartmental methods. Cmax is defined as the maximum (peak) observed concentration following a dose.
Time Frame	Pre-dose, 5 minutes, 1, 4, 8, 24, 72 and 168 hours after the end of infusion on Cycle 1 Day 1 (C1D1) and Cycle 2 Day 1 (C2D1). One cycle = 28 days.
Analysis Population Description	Participants in the pharmacokinetic analysis set (PAS) who received WVT078 and had an available value for the outcome measure. PAS consisted of all participants who provided an evaluable PK profile.

WVT078 3mcg/kg	**WVT078 6mcg/kg**	**WVT078 12mcg/kg**	**WVT078 24mcg/kg**	**WVT078 48mcg/kg**	**WVT078 64mcg/kg**	**WVT078 96mcg/kg**	**WVT078 192mcg/kg**	**WVT078 250mcg/kg**	**WVT078 12mcg/kg + WHG626 2mg**	**WVT078 24mcg/kg + WHG626 2mg**	**WVT078 48mcg/kg + WHG626 2mg**	**WVT078 48mcg/kg + WHG626 4mg**

Arm/Group Description	Arm A: WVT078 3 mcg/kg QW	Arm A: WVT078 6 mcg/kg QW	Arm A: WVT078 12 mcg/kg QW	Arm A: WVT078 24 mcg/kg QW	Arm A: WVT078 48 mcg/kg QW	Arm A: WVT078 64 mcg/kg QW	Arm A: WVT078 96 mcg/kg QW	Arm A: WVT078 192 mcg/kg QW	Arm A: WVT078 250 mcg/kg QW	Arm B: WVT078 12 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 24 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 4 mg 2 days on/5 days off
Number of Participants Analyzed [units: participants]	1	2	2	2	4	1	3	14	4	5	4	10	4
Maximum observed serum concentration (Cmax) of WVT078 (units: ng/mL)	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**
C1D1 (n=1,2,2,2,4,0,2,14,4,4,3,7,2)	98.3	84.7 (51.0%)	179 (1.2%)	624 (8.6%)	1070 (38.0%)		1630 (76.2%)	3880 (38.4%)	4620 (53.2%)	189 (47.9%)	326 (64.0%)	938 (57.1%)	895 (18.6%)
C2D1 (n=1,1,0,1,4,1,3,11,1,1,2,7,2)	114	188		1100	1610 (18.5%)	1820	4870 (53.3%)	5470 (42.3%)	4550	247	339 (23.8%)	1350 (38.5%)	1680 (13.1%)

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Time to maximum observed serum concentration (Tmax) of WVT078

Description	PK parameters were calculated based on WVT078 serum concentrations by using non-compartmental methods. Tmax is defined as the time to reach maximum (peak) observed concentration following a dose. Actual sampling times were considered for the calculation of PK parameters.
Time Frame	Pre-dose, 5 minutes, 1, 4, 8, 24, 72 and 168 hours after the end of infusion on Cycle 1 Day 1 (C1D1) and Cycle 2 Day 1 (C2D1). One cycle = 28 days.
Analysis Population Description	Participants in the pharmacokinetic analysis set (PAS) who received WVT078 and had an available value for the outcome measure. PAS consisted of all participants who provided an evaluable PK profile.

	WVT078 3mcg/kg	**WVT078 6mcg/kg**	**WVT078 12mcg/kg**	**WVT078 24mcg/kg**	**WVT078 48mcg/kg**	**WVT078 64mcg/kg**	**WVT078 96mcg/kg**	**WVT078 192mcg/kg**	**WVT078 250mcg/kg**	**WVT078 12mcg/kg + WHG626 2mg**	**WVT078 24mcg/kg + WHG626 2mg**	**WVT078 48mcg/kg + WHG626 2mg**	**WVT078 48mcg/kg + WHG626 4mg**
Arm/Group Description	Arm A: WVT078 3 mcg/kg QW	Arm A: WVT078 6 mcg/kg QW	Arm A: WVT078 12 mcg/kg QW	Arm A: WVT078 24 mcg/kg QW	Arm A: WVT078 48 mcg/kg QW	Arm A: WVT078 64 mcg/kg QW	Arm A: WVT078 96 mcg/kg QW	Arm A: WVT078 192 mcg/kg QW	Arm A: WVT078 250 mcg/kg QW	Arm B: WVT078 12 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 24 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 4 mg 2 days on/5 days off
Number of Participants Analyzed [units: participants]	1	2	2	2	4	1	3	14	4	5	4	10	4
Time to maximum observed serum concentration (Tmax) of WVT078 (units: hours)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**

C1D1 (n=1,2,2,2,4,0,2,14,4,4,3,7,2)	3.33 (3.33 to 3.33)	2.57 (2.08 to 3.05)	3.97 (2.1 to 5.83)	4.61 (3.12 to 6.1)	2.24 (2.08 to 3.27)		2.21 (2.08 to 2.33)	3 (2.08 to 6.03)	3.03 (2.17 to 7.33)	2.08 (2.02 to 2.9)	2.1 (1.98 to 2.18)	3 (2 to 11)	3.16 (2.08 to 4.23)
C2D1 (n=1,1,0,1,4,1,3,11,1,1,2,7,2)	2.1 (2.1 to 2.1)	2.98 (2.98 to 2.98)		3.1 (3.1 to 3.1)	2.6 (0 to 6.1)	4.15 (4.15 to 4.15)	3.18 (2.12 to 68.4)	2.33 (2.08 to 6.27)	3.07 (3.07 to 3.07)	2.08 (2.08 to 2.08)	2.08 (2.08 to 2.08)	2.2 (1.95 to 57.6)	2.54 (2.07 to 3.02)

Area under the serum concentration-time curve from time zero to the end of a dosing interval (AUCtau) of WVT078

Description	PK parameters were calculated based on WVT078 serum concentrations by using non-compartmental methods. The duration of a dosing interval (tau) was one week. The linear trapezoidal method was used for AUCtau calculation.
Time Frame	Pre-dose, 5 minutes, 1, 4, 8, 24, 72 and 168 hours after the end of infusion on Cycle 1 Day 1 (C1D1) and Cycle 2 Day 1 (C2D1). One cycle = 28 days.
Analysis Population Description	Participants in the pharmacokinetic analysis set (PAS) who received WVT078 and had an available value for the outcome measure. PAS consisted of all participants who provided an evaluable PK profile.

	WVT078 3mcg/kg	**WVT078 6mcg/kg**	**WVT078 12mcg/kg**	**WVT078 24mcg/kg**	**WVT078 48mcg/kg**	**WVT078 64mcg/kg**	**WVT078 96mcg/kg**	**WVT078 192mcg/kg**	**WVT078 250mcg/kg**	**WVT078 12mcg/kg + WHG626 2mg**	**WVT078 24mcg/kg + WHG626 2mg**	**WVT078 48mcg/kg + WHG626 2mg**	**WVT078 48mcg/kg + WHG626 4mg**
Arm/Group Description	Arm A: WVT078 3 mcg/kg QW	Arm A: WVT078 6 mcg/kg QW	Arm A: WVT078 12 mcg/kg QW	Arm A: WVT078 24 mcg/kg QW	Arm A: WVT078 48 mcg/kg QW	Arm A: WVT078 64 mcg/kg QW	Arm A: WVT078 96 mcg/kg QW	Arm A: WVT078 192 mcg/kg QW	Arm A: WVT078 250 mcg/kg QW	Arm B: WVT078 12 mcg/kg QW in combination with WHG626 2 mg	Arm B: WVT078 24 mcg/kg QW in combination with WHG626 2 mg	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 2 mg 2 days	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 4 mg 2 days

										2 days on/5 days off	2 days on/5 days off	on/5 days off	on/5 days off
Number of Participants Analyzed [units: participants]	1	2	2	2	4	1	3	14	4	5	4	10	4
Area under the serum concentration-time curve from time zero to the end of a dosing interval (AUCtau) of WVT078 (units: hr*ng/mL)	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**
C1D1 (n=1,2,2,2,4,0,2,8,3,3,2,6,1)	8370	8080 (27.6%)	14800 (1.1%)	46100 (2.1%)	95600 (37.1%)		140000 (71.4%)	337000 (31.4%)	287000 (54.8%)	16300 (23.4%)	18400 (41.8%)	71500 (62.5%)	75500
C2D1 (n=1,0,0,1,4,1,2,8,1,1,1,6,2)	12400			142000	199000 (16.0%)	194000	488000 (9.7%)	534000 (37.8%)	499000	26300	33100	153000 (48.5%)	180000 (23.6%)

Minimum observed serum concentration (Cmin) of WVT078

Description	PK parameters were calculated based on WVT078 serum concentrations by using non-compartmental methods. Cmin is defined as the minimum observed concentration following a dose.
Time Frame	Pre-dose, 5 minutes, 1, 4, 8, 24, 72 and 168 hours after the end of infusion on Cycle 2 Day 1 (C2D1). One cycle = 28 days.
Analysis Population Description	Participants in the pharmacokinetic analysis set (PAS) who received WVT078 and had an available value for the outcome measure. PAS consisted of all participants who provided an evaluable PK profile.

	WVT078 3mcg/kg	WVT078 6mcg/kg	WVT078 12mcg/kg	WVT078 24mcg/kg	WVT078 48mcg/kg	WVT078 64mcg/kg	WVT078 96mcg/kg	WVT078 192mcg/kg	WVT078 250mcg/kg	WVT078 12mcg/kg + WHG626 2mg	WVT078 24mcg/kg + WHG626 2mg	WVT078 48mcg/kg + WHG626 2mg	WVT078 48mcg/kg + WHG626 4mg
Arm/Group Description	Arm A: WVT078 3 mcg/kg QW	Arm A: WVT078 6 mcg/kg QW	Arm A: WVT078 12 mcg/kg QW	Arm A: WVT078 24 mcg/kg QW	Arm A: WVT078 48 mcg/kg QW	Arm A: WVT078 64 mcg/kg QW	Arm A: WVT078 96 mcg/kg QW	Arm A: WVT078 192 mcg/kg QW	Arm A: WVT078 250 mcg/kg QW	Arm B: WVT078 12 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 24 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 4 mg 2 days on/5 days off
Number of Participants Analyzed [units: participants]	1	1	0	1	3	1	2	11	1	1	2	7	2
Minimum observed serum concentration (Cmin) of WVT078 (units: ng/mL)	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**
C2D1	50.7	87		530	783 (19.3%)	735	1500 (16.1%)	1700 (65.5%)	1880	101	45 (105.8%)	518 (69.2%)	583 (24.5%)

Terminal elimination half-life (T1/2) of WVT078

Description	PK parameters were calculated based on WVT078 serum concentrations by using non-compartmental methods. Elimination half-life (T1/2) values were calculated as Ln (2)/terminal elimination rate constant.
Time Frame	Pre-dose, 5 minutes, 1, 4, 8, 24, 72 and 168 hours after the end of infusion on Cycle 1 Day 1 (C1D1) and Cycle 2 Day 1 (C2D1). One cycle = 28 days.
Analysis Population Description	Participants in the pharmacokinetic analysis set (PAS) who received WVT078 and had an available value for the outcome measure. PAS consisted of all participants who provided an evaluable PK profile.

	WVT078 3mcg/kg	**WVT078 6mcg/kg**	**WVT078 12mcg/kg**	**WVT078 24mcg/kg**	**WVT078 48mcg/kg**	**WVT078 64mcg/kg**	**WVT078 96mcg/kg**	**WVT078 192mcg/kg**	**WVT078 250mcg/kg**	**WVT078 12mcg/kg + WHG626 2mg**	**WVT078 24mcg/kg + WHG626 2mg**	**WVT078 48mcg/kg + WHG626 2mg**	**WVT078 48mcg/kg + WHG626 4mg**
Arm/Group Description	Arm A: WVT078 3 mcg/kg QW	Arm A: WVT078 6 mcg/kg QW	Arm A: WVT078 12 mcg/kg QW	Arm A: WVT078 24 mcg/kg QW	Arm A: WVT078 48 mcg/kg QW	Arm A: WVT078 64 mcg/kg QW	Arm A: WVT078 96 mcg/kg QW	Arm A: WVT078 192 mcg/kg QW	Arm A: WVT078 250 mcg/kg QW	Arm B: WVT078 12 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 24 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 4 mg 2 days on/5 days off
Number of Participants Analyzed [units: participants]	1	2	2	2	4	1	3	14	4	5	4	10	4
Terminal elimination half-life (T1/2) of	**Geometric Mean**	**Geometric Mean**	**Geometric Mean**	**Geometric Mean**	**Geometric Mean**	**Geometric Mean**	**Geometric Mean**	**Geometric Mean**	**Geometric Mean**	**Geometric Mean**	**Geometric Mean**	**Geometric Mean**	**Geometric Mean**

WVT078 (units: hours)	(Geometric Coefficient of Variation)	(Geometric Coefficient of Variation)	(Geometric Coefficient of Variation)	(Geometric Coefficient of Variation)	(Geometric Coefficient of Variation)	(Geometric Coefficient of Variation)	(Geometric Coefficient of Variation)	(Geometric Coefficient of Variation)	(Geometric Coefficient of Variation)	(Geometric Coefficient of Variation)	(Geometric Coefficient of Variation)	(Geometric Coefficient of Variation)	(Geometric Coefficient of Variation)
C1D1 (n=1,2,2,0,4,0,2,13,4,3,2,7,2)	109	152 (30.9%)	91.6 (2.5%)		149 (36.4%)		129 (4.6%)	103 (38.9%)	72.4 (61.0%)	103 (12.2%)	75.8 (28.5%)	128 (39.9%)	81.1 (44.8%)
C2D1 (n=1,0,0,1,3,1,1,10,1,1,1,6,2)	199			186	232 (42.0%)	249	103	132 (32.6%)	181	144	98.9	162 (8.0%)	128 (7.0%)

Maximum observed plasma concentration (Cmax) of WHG626 and its active metabolite GWQ573

Description	PK parameters were calculated by using non-compartmental methods based on WHG626 and its active metabolite GWQ573 plasma concentrations. Cmax is defined as the maximum (peak) observed concentration following a dose.
Time Frame	Cycle 1 Day 1 (C1D1), Cycle 1 Day 2 (C1D2), Cycle 2 Day 1 (C2D1), Cycle 2 Day 2 (C2D2): pre-dose, 1, 1.5, 2, 4, 6 or 8 hours post-dose. 24 hours only on Day 1s; 72 hours only on Day 2s. One cycle = 28 days.
Analysis Population Description	Participants in the pharmacokinetic analysis set (PAS) who received WHG626 and had an available value for the outcome measure. PAS consisted of all participants who provided an evaluable PK profile.

	WVT078 12mcg/kg + WHG626 2mg	WVT078 24mcg/kg + WHG626 2mg	WVT078 48mcg/kg + WHG626 2mg	WVT078 48mcg/kg + WHG626 4mg
Arm/Group Description	Arm B: WVT078 12 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 24 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 4 mg 2 days on/5 days off
Number of Participants Analyzed [units: participants]	5	4	10	4

Maximum observed plasma concentration (Cmax) of WHG626 and its active metabolite GWQ573 (units: ng/mL)	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**
C1D1, WHG626 (n=5,4,10,4)	21.6 (56.0%)	11.4 (165.2%)	10.8 (113.7%)	23.7 (105.3%)
C1D2, WHG626 (n=5,4,9,3)	19.7 (64.8%)	23.3 (50.6%)	15.9 (61.2%)	8.96 (95.2%)
C2D1, WHG626 (n=2,3,9,3)	12.8 (323.6%)	15.4 (42.2%)	17.6 (126.5%)	29.9 (34.2%)
C2D2, WHG626 (n=1,3,9,3)	28.6	16.8 (133.2%)	18.6 (81.1%)	42.5 (13.6%)
C1D1, GWQ573 (n=5,4,10,4)	2.6 (54.2%)	3.18 (120.0%)	2.12 (51.4%)	3.35 (170.5%)
C1D2, GWQ573 (n=5,4,9,3)	2.66 (36.7%)	4 (41.2%)	2.06 (36.1%)	1.82 (68.1%)
C2D1, GWQ573 (n=2,3,9,3)	6.24 (NA%)[1]	3.86 (23.8%)	3.08 (76.1%)	3.99 (57.9%)
C2D2, GWQ573 (n=1,3,9,3)	4.44	4.12 (67.8%)	2.67 (78.7%)	4.48 (10.9%)

[1] Not applicable

Time to maximum observed plasma concentration (Tmax) of WHG626 and its active metabolite GWQ573

Description	PK parameters were calculated by using non-compartmental methods based on WHG626 and its active metabolite GWQ573 plasma concentrations. Tmax is defined as the time to reach maximum (peak) observed concentration following a dose. Actual sampling times were considered for the calculation of PK parameters.
Time Frame	Cycle 1 Day 1 (C1D1), Cycle 1 Day 2 (C1D2), Cycle 2 Day 1 (C2D1), Cycle 2 Day 2 (C2D2): pre-dose, 1, 1.5, 2, 4, 6 or 8 hours post-dose. 24 hours only on Day 1s; 72 hours only on Day 2s. One cycle = 28 days.
Analysis Population Description	Participants in the pharmacokinetic analysis set (PAS) who received WHG626 and had an available value for the outcome measure. PAS consisted of all participants who provided an evaluable PK profile.

	WVT078 12mcg/kg + WHG626 2mg	**WVT078 24mcg/kg + WHG626 2mg**	**WVT078 48mcg/kg + WHG626 2mg**	**WVT078 48mcg/kg + WHG626 4mg**
Arm/Group Description	Arm B: WVT078 12 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 24 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 4 mg 2 days on/5 days off

Number of Participants Analyzed [units: participants]	5	4	10	4
Time to maximum observed plasma concentration (Tmax) of WHG626 and its active metabolite GWQ573 (units: hours)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
C1D1, WHG626 (n=5,4,10,4)	1.42 (0.967 to 2.05)	1.49 (0.917 to 2)	1.63 (1 to 4.23)	1.24 (1 to 1.5)
C1D2, WHG626 (n=5,4,9,3)	4 (1.05 to 169)	1 (0 to 2)	3.45 (1.08 to 13)	4 (0 to 4.25)
C2D1, WHG626 (n=2,3,9,3)	4.73 (3.38 to 6.08)	1.5 (1.03 to 4)	1.5 (1 to 24.3)	1.37 (1 to 1.42)
C2D2, WHG626 (n=1,3,9,3)	75.5 (75.5 to 75.5)	1.68 (1.33 to 8)	1.5 (0 to 28.5)	1.5 (1 to 1.5)
C1D1, GWQ573 (n=5,4,10,4)	1.6 (0.967 to 4.05)	0.892 (0 to 1.98)	2 (0 to 4)	1.5 (1.42 to 1.93)
C1D2, GWQ573 (n=5,4,9,3)	26.4 (1.05 to 169)	1.75 (1 to 168)	8.58 (0 to 193)	8 (0 to 8.25)
C2D1, GWQ573 (n=2,3,9,3)	3.16 (0.233 to 6.08)	2.53 (1.03 to 4)	2.07 (1 to 24.3)	1.93 (1 to 2)
C2D2, GWQ573 (n=1,3,9,3)	75.5 (75.5 to 75.5)	2.42 (0 to 6)	2 (0 to 28.5)	2 (1.5 to 2.02)

Area under the plasma concentration-time curve from time zero to the end of a dosing interval (AUCtau) of WHG626 and its active metabolite GWQ573

Description	PK parameters were calculated by using non-compartmental methods based on WHG626 and its active metabolite GWQ573 plasma concentrations. The duration of a dosing interval (tau) was 24 hours. The linear trapezoidal method was used for AUCtau calculation.
Time Frame	Cycle 1 Day 1 (C1D1), Cycle 1 Day 2 (C1D2), Cycle 2 Day 1 (C2D1), Cycle 2 Day 2 (C2D2): pre-dose, 1, 1.5, 2, 4, 6 or 8 hours post-dose. 24 hours only on Day 1s; 72 hours only on Day 2s. One cycle = 28 days.
Analysis Population Description	Participants in the pharmacokinetic analysis set (PAS) who received WHG626 and had an available value for the outcome measure. PAS consisted of all participants who provided an evaluable PK profile.

	WVT078 12mcg/kg + WHG626 2mg	WVT078 24mcg/kg + WHG626 2mg	WVT078 48mcg/kg + WHG626 2mg	WVT078 48mcg/kg + WHG626 4mg
Arm/Group Description	Arm B: WVT078 12 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 24 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 4 mg 2 days on/5 days off
Number of Participants Analyzed [units: participants]	5	4	10	4
Area under the plasma concentration-time curve from time zero to the end of a dosing interval (AUCtau) of WHG626 and its active metabolite GWQ573 (units: hr*ng/mL)	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**
C1D1, WHG626 (n=3,1,7,3)	163 (27.7%)	63.9	134 (34.5%)	223 (64.8%)
C1D2, WHG626 (n=5,4,9,3)	196 (38.2%)	256 (50.6%)	195 (48.9%)	158 (67.5%)
C2D1, WHG626 (n=1,3,9,3)	576	163 (69.2%)	174 (125.3%)	216 (23.9%)
C2D2, WHG626 (n=1,2,8,3)	251	414 (113.0%)	250 (63.8%)	490 (20.8%)
C1D1, GWQ573 (n=0,0,1,2)			45.5	89.7 (23.3%)
C1D2, GWQ573 (n=5,4,7,2)	32.6 (60.5%)	48.3 (57.9%)	21.9 (103.6%)	54.5 (58.5%)
C2D1, GWQ573 (n=1,1,3,3)	101	91	83.3 (32.1%)	52.5 (3.1%)
C2D2, GWQ573 (n=1,1,2,2)	40.3	116	80.7 (109.9%)	77.8 (20.8%)

Number of participants with anti-WVT078 antibodies

Description The immunogenicity (IG) against WVT078 was assessed in serum using a validated homogeneous enzyme-linked immunosorbent assay (ELISA). Patient anti-drug antibodies (ADA) status was defined as follows: • ADA-negative at baseline: ADA-negative sample at baseline • ADA-positive at baseline: ADA-positive sample at baseline • ADA-negative post-baseline: patient with ADA-negative sample at baseline and at least 1 post baseline sample, all of which are ADA-negative samples • ADA-inconclusive post-baseline = patient who does not qualify as ADA-positive or ADA-negative post-baseline • Treatment-induced ADA-positive = ADA-negative sample at baseline and at least 1 treatment-

induced ADA-positive sample • Treatment-boosted ADA-positive = ADA-positive sample at baseline and at least 1 treatment-boosted ADA-positive sample

Time Frame: Baseline (before first dose) and post-baseline (assessed throughout the treatment up to approximately 44 months).

Analysis Population Description: Participants who received WVT078 with a non-missing baseline IG sample and at least one non-missing post-baseline IG sample.

	WVT078 3mcg/kg	WVT078 6mcg/kg	WVT078 12mcg/kg	WVT078 24mcg/kg	WVT078 48mcg/kg	WVT078 64mcg/kg	WVT078 96mcg/kg	WVT078 192mcg/kg	WVT078 250mcg/kg	WVT078 12mcg/kg + WHG62 6 2mg	WVT078 24mcg/kg + WHG62 6 2mg	WVT078 48mcg/kg + WHG62 6 2mg	WVT078 48mcg/kg + WHG62 6 4mg
Arm/Group Description	Arm A: WVT078 3 mcg/kg QW	Arm A: WVT078 6 mcg/kg QW	Arm A: WVT078 12 mcg/kg QW	Arm A: WVT078 24 mcg/kg QW	Arm A: WVT078 48 mcg/kg QW	Arm A: WVT078 64 mcg/kg QW	Arm A: WVT078 96 mcg/kg QW	Arm A: WVT078 192 mcg/kg QW	Arm A: WVT078 250 mcg/kg QW	Arm B: WVT078 12 mcg/kg QW in combination with WHG62 6 2 mg 2 days on/5 days off	Arm B: WVT078 24 mcg/kg QW in combination with WHG62 6 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG62 6 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG62 6 4 mg 2 days on/5 days off
Number of Participants Analyzed [units: participants]	1	1	2	2	4	1	3	13	3	4	4	8	4
Number of participants	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**

with anti-WVT078 antibodies (units: participants)	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**	**(Percentage)**
ADA-negative at baseline	1 (100%)	1 (100%)	2 (100%)	2 (100%)	3 (75%)	1 (100%)	3 (100%)	13 (100%)	3 (100%)	4 (100%)	4 (100%)	8 (100%)	4 (100%)
ADA-positive at baseline	0 (%)	0 (%)	0 (%)	0 (%)	1 (25%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
ADA-negative post-baseline	1 (100%)	1 (100%)	1 (50%)	2 (100%)	3 (75%)	1 (100%)	3 (100%)	11 (84.62%)	3 (100%)	3 (75%)	4 (100%)	7 (87.5%)	4 (100%)
ADA-inconclusive post-baseline	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Treatment-induced ADA-positive	0 (%)	0 (%)	1 (50%)	0 (%)	0 (%)	0 (%)	0 (%)	2 (15.38%)	0 (%)	1 (25%)	0 (%)	1 (12.5%)	0 (%)
Treatment-boosted ADA-positive	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

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Post-Hoc Outcome Result(s)

All-Collected Deaths

Description	Deaths in the on-treatment and post-treatment safety follow-up (FU) were collected from the first dose of study treatment through 90 days after the last dose. Deaths in the disease progression FU period were collected from 91 days after the last dose of study treatment until the end of study. All deaths refer to the combined total of on-treatment and post-treatment safety follow-up (FU) deaths, as well as deaths in the disease progression FU.
Time Frame	On-treatment and post-treatment safety FU deaths: up to ~47 months (median 4.4) in Arm A, ~32 months (median 5.8) in Arm B. Survival FU deaths: up to ~47 and ~32 months in Arms A and B, respectively.
Analysis Population Description	All participants who received at least one dose of study treatment.

	WVT078 3mcg/kg	**WVT078 6mcg/kg**	**WVT078 12mcg/kg**	**WVT078 24mcg/kg**	**WVT078 48mcg/kg**	**WVT078 64mcg/kg**	**WVT078 96mcg/kg**	**WVT078 192mcg/kg**	**WVT078 250mcg/kg**	**WVT078 12mcg/kg + WHG62 6 2mg**	**WVT078 24mcg/kg + WHG62 6 2mg**	**WVT078 48mcg/kg + WHG62 6 2mg**	**WVT078 48mcg/kg + WHG62 6 4mg**
Arm/Group Description	Arm A: WVT078 3 mcg/kg QW	Arm A: WVT078 6 mcg/kg QW	Arm A: WVT078 12 mcg/kg QW	Arm A: WVT078 24 mcg/kg QW	Arm A: WVT078 48 mcg/kg QW	Arm A: WVT078 64 mcg/kg QW	Arm A: WVT078 96 mcg/kg QW	Arm A: WVT078 192 mcg/kg QW	Arm A: WVT078 250 mcg/kg QW	Arm B: WVT078 12 mcg/kg QW in combination with WHG62 6 2 mg 2 days on/5 days off	Arm B: WVT078 24 mcg/kg QW in combination with WHG62 6 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG62 6 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG62 6 4 mg 2 days on/5 days off
Number of Participants Analyzed [units: participants]	1	2	2	2	4	1	3	14	4	5	4	10	4
All-Collected Deaths (units: participants)													

On-treatment and post-treatment safety FU deaths (n=1,2,22,4,1,3,14,4,5,4,10,4)	0	0	0	0	0	0	0	3	0	3	2	1	0
Disease progression FU deaths (n=1,2,22,4,1,3,11,4,2,2,9,4)	0	0	1	0	0	0	0	1	0	0	0	0	0
All deaths (n=1,2,22,4,1,3,14,4,5,4,10,4)	0	0	1	0	0	0	0	4	0	3	2	1	0

Safety Results

Time Frame	Adverse events and deaths in the on-treatment and post-treatment safety follow-up: from the first dose of study treatment through 90 days after the last dose, up to approximately 47 months (median 4.4) in Arm A and approximately 32 months (median 5.8) in Arm B. Deaths in the disease progression follow-up: from 91 days after the last dose of study treatment until the end of study, up to approximately 47 months in Arm A and approximately 32 months in Arm B.
Source Vocabulary for Table Default	MedDRA (27.1)
Collection Approach for Table Default	Systematic Assessment

All-Cause Mortality

On-treatment and post-treatment follow-up:

	WVT078 3mcg/kg N=1	WVT078 6mcg/kg N=2	WVT078 12mcg/kg N=2	WVT078 24mcg/kg N=2	WVT078 48mcg/kg N=4	WVT078 64mcg/kg N=1	WVT078 96mcg/kg N=3	WVT078 192mcg/kg N=14	WVT078 250mcg/kg N=4	WVT078 12mcg/kg + WHG626 2mg N=5	WVT078 24mcg/kg + WHG626 2mg N=4	WVT078 48mcg/kg + WHG626 2mg N=10	WVT078 48mcg/kg + WHG626 4mg N=4
Arm/Group Description	Arm A: WVT078 3 mcg/kg QW	Arm A: WVT078 6 mcg/kg QW	Arm A: WVT078 12 mcg/kg QW	Arm A: WVT078 24 mcg/kg QW	Arm A: WVT078 48 mcg/kg QW	Arm A: WVT078 64 mcg/kg QW	Arm A: WVT078 96 mcg/kg QW	Arm A: WVT078 192 mcg/kg QW	Arm A: WVT078 250 mcg/kg QW	Arm B: WVT078 12 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 24 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 4 mg 2 days on/5 days off
Total Number Affected	0	0	0	0	0	0	0	3	0	3	2	1	0
Total Number At Risk	1	2	2	2	4	1	3	14	4	5	4	10	4

Disease progression follow-up:

	WVT078 3mcg/kg N=1	WVT078 6mcg/kg N=2	WVT078 12mcg/kg N=2	WVT078 24mcg/kg N=2	WVT078 48mcg/kg N=4	WVT078 64mcg/kg N=1	WVT078 96mcg/kg N=3	WVT078 192mcg/kg N=11	WVT078 250mcg/kg N=4	WVT078 12mcg/kg + WHG626 2mg N=2	WVT078 24mcg/kg + WHG626 2mg N=2	WVT078 48mcg/kg + WHG626 2mg N=9	WVT078 48mcg/kg + WHG626 4mg N=4
Arm/Group Description	Arm A: WVT078 3 mcg/kg QW	Arm A: WVT078 6 mcg/kg QW	Arm A: WVT078 12 mcg/kg QW	Arm A: WVT078 24 mcg/kg QW	Arm A: WVT078 48 mcg/kg QW	Arm A: WVT078 64 mcg/kg QW	Arm A: WVT078 96 mcg/kg QW	Arm A: WVT078 192 mcg/kg QW	Arm A: WVT078 250 mcg/kg QW	Arm B: WVT078 12 mcg/kg QW in	Arm B: WVT078 24 mcg/kg QW in	Arm B: WVT078 48 mcg/kg QW in	Arm B: WVT078 48 mcg/kg QW in

										combination with WHG626 2 mg 2 days on/5 days off	combination with WHG626 2 mg 2 days on/5 days off	combination with WHG626 2 mg 2 days on/5 days off	combination with WHG626 4 mg 2 days on/5 days off
Total Number Affected	0	0	1	0	0	0	0	1	0	0	0	0	0
Total Number At Risk	1	2	2	2	4	1	3	11	4	2	2	9	4

Serious Adverse Events

Time Frame	Adverse events and deaths in the on-treatment and post-treatment safety follow-up: from the first dose of study treatment through 90 days after the last dose, up to approximately 47 months (median 4.4) in Arm A and approximately 32 months (median 5.8) in Arm B. Deaths in the disease progression follow-up: from 91 days after the last dose of study treatment until the end of study, up to approximately 47 months in Arm A and approximately 32 months in Arm B.
Source Vocabulary for Table Default	MedDRA (27.1)
Collection Approach for Table Default	Systematic Assessment

	WVT078 3mcg/	**WVT078 6mcg/**	**WVT078 12mcg/**	**WVT078 24mcg/**	**WVT078 48mcg**	**WVT078 64mcg/k**	**WVT078 96mcg**	**WVT078 192mcg**	**WVT078 250mcg**	**WVT078 12mcg/kg +**	**WVT078 24mcg/kg +**	**WVT078 48mcg/kg +**	**WVT078 48mcg/kg +**

	kg N=1	kg N=2	kg N=2	kg N=2	/kg N=4	g N=1	/kg N=3	/kg N=14	/kg N=4	WHG626 2mg N=5	WHG626 2mg N=4	WHG626 2mg N=10	WHG626 4mg N=4
Arm/Group Description	Arm A: WVT078 3 mcg/kg QW	Arm A: WVT078 6 mcg/kg QW	Arm A: WVT078 12 mcg/kg QW	Arm A: WVT078 24 mcg/kg QW	Arm A: WVT078 48 mcg/kg QW	Arm A: WVT07864 mcg/kg QW	Arm A: WVT078 96 mcg/kg QW	Arm A: WVT078 192 mcg/kg QW	Arm A: WVT078 250 mcg/kg QW	Arm B: WVT07812 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT07824 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT07848 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT07848 mcg/kg QW in combination with WHG626 4 mg 2 days on/5 days off
Total # Affected by any Serious Adverse Event	0	0	2	2	0	1	0	10	4	2	4	7	4
Total # at Risk by any Serious Adverse Event	1	2	2	2	4	1	3	14	4	5	4	10	4
Blood and lymphatic system disorders													
Febrile neutropenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (7.14 %)	1 (25.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Thrombocytopenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)
Cardiac disorders													
Atrial fibrillation	0 (0.00 %)	0 (0.00 %)	1 (50.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Coronary artery disease	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ventricular extrasystoles	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ventricular tachycardia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ear and labyrinth disorders													
Deafness bilateral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)
Gastrointestinal disorders													
Diarrhoea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)
Enteritis	0 (0.00 %)	0 (0.00 %)	1 (50.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gastrointestinal haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
General disorders and administration site conditions													
Influenza like illness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pyrexia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Immune system disorders													
Cytokine release syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.0 0%)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	3 (21.43 %)	1 (25.00 %)	0 (0.00 %)	1 (25.00 %)	3 (30.00 %)	1 (25.00 %)
Infections and infestations													
Clostridium difficile colitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.00 %)
COVID-19	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.00 %)
Device related infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.0 0%)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Device related sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.00 %)
Enterocolitis infectious	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Mastoiditis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)
Pneumococcal sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.00 %)
Pneumocystis jirovecii pneumonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (7.14 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pneumonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	3 (75.00 %)	1 (10.00 %)	0 (0.00 %)
Pneumonia pneumococcal	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Pulmonary sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rhinovirus infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)
Salmonellosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)
Sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	1 (20.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Injury, poisoning and procedural complications													
Infusion related reaction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00 %)	2 (50.00 %)	0 (0.00 %)	0 (0.00 %)
Radius fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Investigations													
Lipase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)
Metabolism and nutrition disorders													
Hypocalcaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyponatraemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tumour lysis syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Musculoskeletal and connective													

tissue disorders													
Muscular weakness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)
Osteonecrosis of jaw	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)													
B-cell lymphoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Epstein-Barr virus associated lymphoproliferative disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Plasma cell leukaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)
Squamous cell carcinoma of skin	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.00 %)
Nervous system disorders													
Presyncope	0 (0.00 %)	0 (0.00 %)	1 (50.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Syncope	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.00 %)

Renal and urinary disorders													
Acute kidney injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (7.14 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal failure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tubulointerstitial nephritis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vascular disorders													
Arterial thrombosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00%)	0 (0.00 %)	0 (0.00 %)	1 (25.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Other (Not Including Serious) Adverse Events

Time Frame	Adverse events and deaths in the on-treatment and post-treatment safety follow-up: from the first dose of study treatment through 90 days after the last dose, up to approximately 47 months (median 4.4) in Arm A and approximately 32 months (median 5.8) in Arm B. Deaths in the disease progression follow-up: from 91 days after the last dose of study treatment until the end of study, up to approximately 47 months in Arm A and approximately 32 months in Arm B.
Source Vocabulary for Table Default	MedDRA (27.1)
Collection Approach for Table Default	Systematic Assessment

Frequent Event Reporting Threshold 5%

	WVT078 3mcg/kg N=1	**WVT078 6mcg/kg N=2**	**WVT078 12mcg/kg N=2**	**WVT078 24mcg/kg N=2**	**WVT078 48mcg/kg N=4**	**WVT078 64mcg/kg N=1**	**WVT078 96mcg/kg N=3**	**WVT078 192mcg/kg N=14**	**WVT078 250mcg/kg N=4**	**WVT078 12mcg/kg + WHG626 2mg N=5**	**WVT078 24mcg/kg + WHG626 2mg N=4**	**WVT078 48mcg/kg + WHG626 2mg N=10**	**WVT078 48mcg/kg + WHG626 4mg N=4**
Arm/Group Description	Arm A: WVT078 3 mcg/kg QW	Arm A: WVT078 6 mcg/kg QW	Arm A: WVT078 12 mcg/kg QW	Arm A: WVT078 24 mcg/kg QW	Arm A: WVT078 48 mcg/kg QW	Arm A: WVT078 64 mcg/kg QW	Arm A: WVT078 96 mcg/kg QW	Arm A: WVT078 192 mcg/kg QW	Arm A: WVT078 250 mcg/kg QW	Arm B: WVT078 12 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 24 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 2 mg 2 days on/5 days off	Arm B: WVT078 48 mcg/kg QW in combination with WHG626 4 mg 2 days on/5 days off
Total # Affected by any Other Adverse Event	1	2	2	2	4	1	3	13	4	5	4	10	4
Total # at Risk by any Other Adverse Event	1	2	2	2	4	1	3	14	4	5	4	10	4
Blood and lymphatic system disorders													
Anaemia	0 (0.00 %)	0 (0.00 %)	2 (100.00%)	0 (0.00 %)	1 (25.0 0%)	1 (100.00%)	1 (33.3 3%)	8 (57.1 4%)	2 (50.0 0%)	3 (60.0 0%)	2 (50.0 0%)	3 (30.0 0%)	2 (50.0 0%)
Hypoglobulinaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Iron deficiency anaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Leukopenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	3 (21.4 3%)	1 (25.0 0%)	0 (0.00 %)	1 (25.0 0%)	1 (10.0 0%)	0 (0.00 %)
Lymphopenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	1 (100. 00%)	0 (0.00 %)	3 (21.4 3%)	1 (25.0 0%)	0 (0.00 %)	2 (50.0 0%)	1 (10.0 0%)	0 (0.00 %)
Neutropenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.0 0%)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	6 (42.8 6%)	4 (100. 00%)	1 (20.0 0%)	1 (25.0 0%)	7 (70.0 0%)	3 (75.0 0%)
Neutrophilia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Thrombocytopenia	0 (0.00 %)	0 (0.00 %)	1 (50.0 0%)	0 (0.00 %)	1 (25.0 0%)	1 (100. 00%)	1 (33.3 3%)	7 (50.0 0%)	2 (50.0 0%)	2 (40.0 0%)	3 (75.0 0%)	4 (40.0 0%)	3 (75.0 0%)
Cardiac disorders													
Atrioventricular block first degree	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Bradycardia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Cardiac failure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Palpitations	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Sinus tachycardia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Tachycardia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.3 3%)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ear and labyrinth disorders													
Ear discomfort	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)

Ear pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (20.0 0%)	0 (0.00 %)
Hypoacusis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Middle ear inflammation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Tinnitus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Vertigo	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Endocrine disorders													
Hyperparathyroidism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Hypothyroidism	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Eye disorders													
Blepharitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Cataract	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Conjunctival haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Diplopia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dry eye	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Keratitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Meibomian gland dysfunction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Swelling of eyelid	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vision blurred	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Gastrointestinal disorders													
Abdominal pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (20.0 0%)	1 (25.0 0%)
Abdominal pain upper	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Angular cheilitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Constipation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	1 (25.0 0%)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Dental caries	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Diarrhoea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.0 0%)	1 (25.0 0%)	1 (100. 00%)	1 (33.3 3%)	2 (14.2 9%)	2 (50.0 0%)	1 (20.0 0%)	0 (0.00 %)	5 (50.0 0%)	3 (75.0 0%)
Dry mouth	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Dyspepsia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	1 (10.0 0%)	0 (0.00 %)
Faecaloma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Flatulence	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Gastric polyps	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)

Gastrooesophageal reflux disease	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Glossodynia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nausea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	1 (33.3 3%)	2 (14.2 9%)	2 (50.0 0%)	2 (40.0 0%)	1 (25.0 0%)	3 (30.0 0%)	2 (50.0 0%)
Odynophagia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Oral pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	1 (25.0 0%)
Stomatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (14.2 9%)	1 (25.0 0%)	0 (0.00 %)	1 (25.0 0%)	1 (10.0 0%)	0 (0.00 %)
Vomiting	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	1 (7.14 %)	2 (50.0 0%)	3 (60.0 0%)	0 (0.00 %)	2 (20.0 0%)	2 (50.0 0%)
General disorders and administration site conditions													
Asthenia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (14.2 9%)	1 (25.0 0%)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	1 (25.0 0%)
Chest pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (21.4 3%)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	1 (10.0 0%)	0 (0.00 %)
Chills	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	1 (100. 00%)	1 (33.3 3%)	2 (14.2 9%)	1 (25.0 0%)	0 (0.00 %)	1 (25.0 0%)	3 (30.0 0%)	2 (50.0 0%)
Face oedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Facial pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Fatigue	1 (100. 00%)	2 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	2 (14.2 9%)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	2 (20.0 0%)	0 (0.00 %)
Influenza like illness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)

Injection site haematoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Malaise	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Nodule	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Non-cardiac chest pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	2 (14.2 9%)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Oedema peripheral	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.0 0%)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	3 (21.4 3%)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	3 (30.0 0%)	1 (25.0 0%)
Pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Pyrexia	0 (0.00 %)	0 (0.00 %)	1 (50.0 0%)	2 (100. 00%)	1 (25.0 0%)	1 (100. 00%)	2 (66.6 7%)	8 (57.1 4%)	3 (75.0 0%)	2 (40.0 0%)	1 (25.0 0%)	6 (60.0 0%)	2 (50.0 0%)
Swelling	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vessel puncture site haematoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Hepatobiliary disorders													
Hyperbilirubinaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Immune system disorders													
Cytokine release syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.0 0%)	4 (100. 00%)	1 (100. 00%)	1 (33.3 3%)	10 (71. 43%)	3 (75.0 0%)	2 (40.0 0%)	1 (25.0 0%)	5 (50.0 0%)	4 (100. 00%)
Hypersensitivity	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Hypogammaglobulinaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.3 3%)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (20.0 0%)	1 (25.0 0%)

Seasonal allergy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.3 3%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Infections and infestations													
Bacteraemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Clostridium difficile colitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Conjunctivitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
COVID-19	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	1 (20.0 0%)	0 (0.00 %)	2 (20.0 0%)	0 (0.00 %)
Cytomegalovirus infection reactivation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (50.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Diarrhoea infectious	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Ear infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Ear lobe infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Enterocolitis infectious	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Fungal infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Gastroenteritis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Gastroenteritis salmonella	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Gingivitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Hepatitis E	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Herpes simplex	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Herpes zoster	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Influenza	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Localised infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Nail infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (20.0 0%)	0 (0.00 %)
Nasopharyngitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	1 (7.14 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Onychomycosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Oral candidiasis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Oral herpes	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Otitis media	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Parainfluenzae virus infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pharyngitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pneumonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	1 (25.0 0%)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	1 (25.0 0%)
Post procedural infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)

Pustule	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rash pustular	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Respiratory syncytial virus infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Respiratory tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Rhinitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rhinovirus infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	1 (25.0 0%)
Sepsis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sinusitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	3 (30.0 0%)	1 (25.0 0%)
Skin infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.3 3%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tinea pedis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Upper respiratory tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.3 3%)	1 (7.14 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	4 (40.0 0%)	1 (25.0 0%)
Urinary tract infection	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Injury, poisoning and procedural complications													
Contusion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Fall	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	1 (25.0 0%)

Foot fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Humerus fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Immunisation reaction	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Infusion related reaction	0 (0.00 %)	0 (0.00 %)	1 (50.0 0%)	1 (50.0 0%)	1 (25.0 0%)	1 (100. 00%)	2 (66.6 7%)	0 (0.00 %)	1 (25.0 0%)	1 (20.0 0%)	0 (0.00 %)	2 (20.0 0%)	0 (0.00 %)
Joint injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Limb injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nail avulsion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Procedural pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Procedural vomiting	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Rib fracture	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin wound	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Wound	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Investigations													
Alanine aminotransferase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	1 (100. 00%)	0 (0.00 %)	6 (42.8 6%)	3 (75.0 0%)	1 (20.0 0%)	1 (25.0 0%)	2 (20.0 0%)	1 (25.0 0%)
Amylase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	1 (100. 00%)	0 (0.00 %)	1 (7.14 %)	1 (25.0 0%)	1 (20.0 0%)	0 (0.00 %)	2 (20.0 0%)	0 (0.00 %)

Aspartate aminotransferase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	1 (100. 00%)	1 (33.3 3%)	6 (42.8 6%)	3 (75.0 0%)	1 (20.0 0%)	1 (25.0 0%)	2 (20.0 0%)	0 (0.00 %)
Blood alkaline phosphatase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	1 (100. 00%)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	1 (10.0 0%)	1 (25.0 0%)
Blood bilirubin increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.3 3%)	1 (7.14 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Blood creatine increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood creatinine increased	0 (0.00 %)	1 (50.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (21.4 3%)	1 (25.0 0%)	0 (0.00 %)	1 (25.0 0%)	2 (20.0 0%)	1 (25.0 0%)
Blood fibrinogen decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood folate decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Blood lactate dehydrogenase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	1 (7.14 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	2 (20.0 0%)	1 (25.0 0%)
Blood pressure increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Blood urea increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
C-reactive protein increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	3 (21.4 3%)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Cytomegalovirus test positive	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Electrocardiogram abnormal	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Electrocardiogram QT prolonged	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)

Gamma-glutamyltransferase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	1 (100. 00%)	1 (33.3 3%)	3 (21.4 3%)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Haemoglobin decreased	0 (0.00 %)	0 (0.00 %)	1 (50.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Heart rate increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Herpes simplex test positive	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lipase increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.0 0%)	1 (25.0 0%)	1 (100. 00%)	1 (33.3 3%)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	4 (40.0 0%)	2 (50.0 0%)
Liver function test increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Lymphocyte count decreased	0 (0.00 %)	0 (0.00 %)	1 (50.0 0%)	0 (0.00 %)	2 (50.0 0%)	0 (0.00 %)	1 (33.3 3%)	0 (0.00 %)	1 (25.0 0%)	1 (20.0 0%)	1 (25.0 0%)	1 (10.0 0%)	1 (25.0 0%)
Neutrophil count increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	1 (7.14 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Platelet count decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Polymerase chain reaction positive	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Procalcitonin increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Troponin increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Weight decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (20.0 0%)	1 (25.0 0%)
Weight increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
White blood cell count abnormal	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

White blood cell count decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.3 3%)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	1 (10.0 0%)	1 (25.0 0%)
White blood cell count increased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Metabolism and nutrition disorders													
Decreased appetite	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (14.2 9%)	1 (25.0 0%)	0 (0.00 %)	1 (25.0 0%)	5 (50.0 0%)	2 (50.0 0%)
Dehydration	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Fluid retention	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Hypercalcaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (14.2 9%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Hypercholesterol aemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Hyperglycaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Hyperphosphata emia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypertriglyceride emia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Hyperuricaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	1 (25.0 0%)
Hypoalbuminae mia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (20.0 0%)	1 (25.0 0%)
Hypocalcaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	1 (25.0 0%)	0 (0.00 %)	1 (25.0 0%)	1 (10.0 0%)	0 (0.00 %)
Hypokalaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	1 (33.3 3%)	2 (14.2 9%)	2 (50.0 0%)	0 (0.00 %)	2 (50.0 0%)	2 (20.0 0%)	1 (25.0 0%)

Hypomagnesaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33%)	0 (0.00 %)	1 (25.00%)	0 (0.00 %)	1 (25.00%)	2 (20.00%)	2 (50.00%)
Hyponatraemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (33.33%)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (20.00%)	0 (0.00 %)
Hypophosphataemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00%)	1 (25.00%)	1 (100.00%)	1 (33.33%)	4 (28.57%)	2 (50.00%)	0 (0.00 %)	1 (25.00%)	3 (30.00%)	1 (25.00%)
Hypoproteinaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	0 (0.00 %)
Iron deficiency	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.00%)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	1 (25.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.00%)
Obesity	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vitamin B12 deficiency	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	0 (0.00 %)
Vitamin D deficiency	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Musculoskeletal and connective tissue disorders													
Arthralgia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.00%)	1 (100.00%)	0 (0.00 %)	3 (21.43%)	1 (25.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.00%)
Arthritis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	0 (0.00 %)
Back pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.00%)	1 (100.00%)	1 (33.33%)	2 (14.29%)	0 (0.00 %)	1 (20.00%)	0 (0.00 %)	1 (10.00%)	2 (50.00%)
Bone pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (20.00%)	0 (0.00 %)
Flank pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.00%)	0 (0.00 %)
Groin pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Muscle spasms	0 (0.00 %)	1 (50.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Muscular weakness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	2 (20.0 0%)	1 (25.0 0%)
Musculoskeletal chest pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Myalgia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Neck pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Pain in extremity	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	2 (14.2 9%)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	3 (30.0 0%)	0 (0.00 %)
Rotator cuff syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Sacral pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Synovial cyst	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tendonitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Tenosynovitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)													
Tumour pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Nervous system disorders													
Disturbance in attention	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)

Dizziness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Dysgeusia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	1 (25.0 0%)
Headache	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	1 (100. 00%)	0 (0.00 %)	3 (21.4 3%)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	4 (40.0 0%)	1 (25.0 0%)
Hyperaesthesia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Hypoaesthesia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Immune effector cell-associated neurotoxicity syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Nervous system disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Paraesthesia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Peripheral motor neuropathy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Peripheral sensory neuropathy	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	1 (25.0 0%)
Presyncope	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Somnolence	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tremor	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Psychiatric disorders													
Agitation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)

Anxiety	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Confusional state	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Delirium	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Depression	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Hallucination	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Insomnia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	1 (25.0 0%)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Tearfulness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal and urinary disorders													
Acute kidney injury	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	1 (25.0 0%)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Azotaemia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Pollakiuria	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Renal failure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Renal impairment	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Tubulointerstitial nephritis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Urinary incontinence	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Urine abnormality	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)

Urine flow decreased	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Reproductive system and breast disorders													
Pelvic pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vaginal haemorrhage	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vulvovaginal dryness	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Respiratory, thoracic and mediastinal disorders													
Acute respiratory failure	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Cough	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	1 (25.0 0%)	0 (0.00 %)	1 (25.0 0%)	3 (30.0 0%)	1 (25.0 0%)
Diaphragmalgia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Dysphonia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Dyspnoea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	1 (33.3 3%)	1 (7.14 %)	1 (25.0 0%)	0 (0.00 %)	1 (25.0 0%)	2 (20.0 0%)	1 (25.0 0%)
Dyspnoea exertional	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Epistaxis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypoxia	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	1 (33.3 3%)	2 (14.2 9%)	2 (50.0 0%)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	1 (25.0 0%)

Nasal congestion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	1 (25.0 0%)
Oropharyngeal pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	1 (25.0 0%)
Pleural effusion	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Productive cough	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Pulmonary oedema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Rhinorrhoea	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sinus pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Sneezing	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Stridor	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (20.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Skin and subcutaneous tissue disorders													
Actinic keratosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Dermatitis psoriasiform	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Dry skin	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Eczema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Erythema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Hand dermatitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hyperhidrosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Hypotrichosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Nail disorder	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Night sweats	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	1 (25.0 0%)
Petechiae	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)
Plantar erythema	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Prurigo	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Pruritus	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Rash	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	2 (50.0 0%)	1 (20.0 0%)	2 (50.0 0%)	2 (20.0 0%)	1 (25.0 0%)
Rash erythematous	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Rash maculo-papular	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.0 0%)	1 (25.0 0%)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	2 (50.0 0%)
Rash papular	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)
Skin exfoliation	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	2 (50.0 0%)	2 (20.0 0%)	0 (0.00 %)
Skin mass	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vascular disorders													

Arterial thrombosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Capillary leak syndrome	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Deep vein thrombosis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Flushing	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	0 (0.00 %)
Haematoma	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Hypertension	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	1 (33.3 3%)	2 (14.2 9%)	1 (25.0 0%)	0 (0.00 %)	0 (0.00 %)	2 (20.0 0%)	0 (0.00 %)
Hypotension	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (50.0 0%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	3 (21.4 3%)	2 (50.0 0%)	0 (0.00 %)	0 (0.00 %)	1 (10.0 0%)	1 (25.0 0%)
Phlebitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Thrombophlebitis	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (100. 00%)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)
Vascular pain	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (7.14 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)

Conclusion:

In conclusion, WVT078 administered alone and in combination with WHG626 were found to be safe in participants with relapsed and/or refractory MM. The AE/SAEs reported were consistent with the mechanisms of action of both study drugs. Addressing the resistance mechanisms to these agents remains an important goal because the majority of participants eventually relapse or become refractory to treatments. Findings from this study add to the body of evidence of B-cell maturation antigen (BCMA) engaging agents and pave the way for further exploration of gamma secretase inhibitors (GSI) as their combination partner for the treatment of relapsed and/or refractory MM.

NOVARTIS

Date of Clinical Trial Report

24-Jul-2025