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Sponsor

Novartis Pharmaceuticals

Generic Drug Name

VOB560 and MIK665

Trial Indication(s)

Relapsed/refractory (R/R) non-Hodgkin lymphoma, R/R acute myeloid leukemia and R/R multiple myeloma

Protocol Number

CVOB560A12101

Protocol Title

A phase Ib, multicenter study of VOB560 in combination with MIK665 in patients with relapsed/refractory non-Hodgkin lymphoma, relapsed/refractory acute myeloid leukemia, or relapsed/refractory multiple myeloma.

Clinical Trial Phase

Phase 1

Phase of Drug Development

Phase 1

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Study Start/End Dates

Study Start Date: June 23, 2021 (Actual)
Primary Completion Date: July 23, 2024 (Actual)
Study Completion Date: July 23, 2024 (Actual)

Reason for Termination (If applicable)

Recruitment for the CVOB560A12101 study was halted and eventually terminated due to strategic reasons.

At the time of the recruitment halt, a total of 29 acute myeloid leukemia patients, 4 non-Hodgkin lymphoma patients and 4 multiple myeloma patients were treated in the escalation part of the trial. The expansion part was not opened in the CVOB560A12101 study.

Study Design/Methodology

This is an open-label, non-randomized multi-center phase Ib study with a dose escalation part followed by a dose expansion part. Patients received VOB560 in combination with MIK665 in a once per week (QW) schedule over 21 days cycle.

The dose escalation part included two study arms:

- Arm A: relapsed and/or refractory non-Hodgkin lymphoma (R/R NHL) and relapsed and/or refractory multiple myeloma (R/R MM)
- Arm B: relapsed and/or refractory acute myeloid leukemia (R/R AML)

An adaptive Bayesian hierarchical logistic regression model (BHLRM) using the escalation with overdose control (EWOC) principle guided dose escalation to determine the maximum tolerated dose(s) (MTDs) and/or recommended dose(s) for expansion (RDs). One BHLRM was used for R/R MM and R/R NHL patients, while a separate BHLRM was used for R/R AML patients.

Due to a business decision, the trial was terminated earlier than planned. As a result, the MTD or RD was not achieved at the time of termination. The dose expansion part of the study was not conducted.

Centers

9 centers in 9 countries/regions: Belgium(1), Italy(1), Israel(1), Japan(1), Korea, Republic of(1), Hong Kong(1), Finland(1), Spain(1), United States(1)

Objectives:

The primary objective of the study was to characterize safety and tolerability of VOB560 in combination with MIK665 in hematological malignancies and to identify maximal tolerated doses (MTDs) and/or recommended doses (RDs and regimens for all indications).

The secondary objectives of the study were:

- To evaluate the preliminary anti-tumor activity of VOB560 and MIK665 in combination
- To assess the pharmacokinetic (PK) profile of VOB560 and MIK665 in combination

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

For this study, the terms “investigational drug” or “study drug” refers to VOB560 or MIK665. “Study treatment” refers to the specific combination treatment i.e. VOB560 and MIK665 in combination.

VOB560 and MIK665 were administered via intravenous (i.v.) infusion for 30 minutes each, with a 30-minute pause in between, once every week in a 21-day cycle.

Patients could continue treatment with MIK665 and VOB560 until they experienced unacceptable toxicity that precluded any further treatment, disease progression, and/or treatment was discontinued at the discretion of the investigator or by patient request.

Statistical Methods

The data from all centers that participated in this protocol was used. Categorical data or qualitative characteristics of a patient (e.g., gender, race, patient disposition, etc.) were summarized by frequency count (number of patients) and percentages. Percentages were calculated using the number of patients in the relevant population or subgroup as the denominator. Continuous data (e.g., age, etc.) were summarized by appropriate descriptive statistics (e.g., mean and standard deviation).

Efficacy

Diagnosis and Tumor Response for NHL: World Health Organization (WHO) classification at diagnosis and tumor response determined locally using Cheson et al 2014 guidelines.

Diagnosis and Response Evaluation for AML: WHO definition of AML recorded in Case Report Forms (CRFs), with response assessments based on International Working Group (IWG) and European Leukemia Network (ELN) criteria.

Diagnosis and Efficacy Assessments for MM: International Myeloma Working Group (IMWG) classifications at diagnosis, with assessments including M-protein, immunoglobulins, and free light chain analysis.

Pharmacokinetics

To assess PK of VOB560 and MIK665 administered in combination, blood samples were collected. All time points listed were related to VOB560 treatment (1st drug to be infused in the combination treatment with MIK665).

For the weekly administration (QW) schedule in a 21-day cycle, full PK profile for both compounds were planned on Cycle 1 Day 1/Day 2 (C1D1/D2) and Cycle 1 Day 8/Day 9 (C1D8/D9) for assessing main PK parameters. PK parameters were calculated using non-compartmental methods.

Safety

Safety assessments consisted of the incidence of adverse events and serious adverse events, including changes in lab values, vital signs, and electrocardiograms (ECGs), as well as the incidence of dose-limiting toxicities (DLTs) during the first cycle of treatment with VOB560 and MIK665 in combination (dose escalation part only).

Tolerability was assessed based on dose interruptions, reductions, and dose intensity.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:

- Diagnosis of one of the following hematologic malignancies:
  - relapsed and/or refractory patients with non-Hodgkin lymphoma with radiographically measurable disease with a clearly demarcated nodal lesion at least 1.5 cm in its largest dimension or a target extra nodal lesion at least 1.0 cm in its largest dimension
  - relapsed and/or refractory patients with MM treated with at least 2 prior regimens, including an IMiD, a proteasome inhibitor proteasome inhibitor, and anti-CD38 antibody (if available) and not eligible for treatment with other regimens known to provide clinical benefit, as determined by the investigator.
  - relapsed and/or refractory patients with Acute Myeloid Leukemia (AML), pathologically confirmed diagnosis as defined by the WHO Classification and with ≥ 5% blasts in bone marrow. Following ≥ 1 prior therapies who have relapsed or exhibited refractory disease (primary failure) and are deemed by the investigator not to be candidates for standard therapy, including re-induction with cytarabine or other established therapeutic regimens for patients with AML (patients who are suitable for standard re-induction chemotherapy or hematopoietic stem cell transplantation and willing to receive it are excluded).
- Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 2.
- Patient must be a candidate for serial bone marrow aspirate and/or biopsy according to the institution's guidelines and be willing to undergo a bone marrow aspirate and/or biopsy at screening, during and at the end of therapy on this study.

Exclusion Criteria:

1. History of severe hypersensitivity reactions to any ingredient of study treatment and/or their excipients.

2. Systemic antineoplastic therapy (including cytotoxic chemotherapy, alpha-interferon, kinase inhibitors or other targeted small molecules, and toxin immunoconjugates) or any experimental therapy within 14 days or 5 half-lives, whichever is shorter, before the first dose of study treatment.
3. High-risk patients for Tumor Lysis Syndrome according to Cairo et al 2010 criteria or local guidelines.
4. Impaired cardiac function or clinically significant cardiac disease, or history or current diagnosis of ECG abnormalities indicating significant risk of safety including any of the following:
    a. Concomitant clinically significant cardiac arrhythmias, e.g. sustained ventricular tachycardia, and clinically significant second- or third-degree AV block without a pacemaker
    b. Any history of clinical important abnormalities in rhythm, conduction or morphology of resting ECG e.g. complete left bundle branch block, third degree heart block
    c. Any factors that increase the risk of QTc prolongation or risk of arrhythmic events such as heart failure, significant hypokalemia, congenital long QT syndrome, family history of long QT syndrome or unexplained sudden death under 40 years of age
    d. Resting QTcF ≥450 msec (male) or ≥460 msec (female) at pre-treatment
    e. Use of agents known to prolong the QT interval unless it can be permanently discontinued for the duration of study.
    f. Abnormal echocardiogram (ECHO) or multi-gated acquisition scan (MUGA) at baseline (left ventricular ejection fraction [LVEF] <50%)
    g. Symptomatic congestive heart failure (New York Heart Association ≥ 3)
    h. Findings observed in the baseline cardiac MRI that might reflect an increased risk for cardiac adverse events.
5. Use of hematopoietic colony-stimulating growth factors (e.g. G-CSF, GM-CSF, M-CSF), thrombopoietin mimetics or erythroid stimulating agents ≤ 2 weeks prior to start of study treatment. If thrombopoietin mimetics or erythroid

stimulating agents were initiated more than 2 weeks prior to the first dose of study treatment and the patient is on a stable dose, they can be maintained.

6. For AML patients: Peripheral blast counts > 25,000 blasts / mm3. Patients can receive hydroxyurea to control the peripheral blast counts as long as hydroxyurea can be stopped at least 24 hours prior to obtaining PD biomarkers at screening/baseline. Hydroxyurea can be restarted after sampling if clinically indicated to control blasts prior to the start of study treatment markers.
7. For patients with R/R NHL and R/R MM:
   - Absolute Neutrophil count < 1.0 x 109/L
   - Platelets count < 50 x 109/ L
   - Hemoglobin < 8 g/dl
8. Autologous stem cell transplant within 3 months before the first dose of study treatment.
9. Patients who have undergone a prior allogeneic stem cell transplant before the first dose of study treatment.
10. History of or current interstitial lung disease or pneumonitis grade ≥ 2.
11. . Impaired hepatic and renal function defined as:
    - Serum aspartate aminotransferase (AST) or alanine aminotransferase (ALT) > 1.5 x upper limit of normal (ULN)
    - Bilirubin >1.5 x ULN (unless bilirubin rise is due to Gilbert's syndrome or of non-hepatic origin)
    - Creatinine clearance <50 mL/min (calculated using Cockroft-Gault formula, or measured).
12. Lipase >1.5 x ULN or serum amylase >1.5 x ULN and no history of pancreatitis.
13. Increased cardiac troponin above the manufacturer's 99th percentile upper reference limit for local assay at screening

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Participant Flow Table

Overall Study

	AML: VOB560 25mgQW + MIK665 25mgQW	AML: VOB560 25mgQW + MIK665 50mgQW	AML: VOB560 50mgQW + MIK665 25mgQW	AML: VOB560 50mgQW + MIK665 50mgQW	NHL and MM: VOB560 25mgQW + MIK665 25mgQW	NHL and MM: VOB560 25mgQW + MIK665 50mgQW	NHL and MM: VOB560 50mgQW + MIK665 25mgQW	Total
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	
Started	5	6	12	6	3	1	4	37
Completed	0	0	0	0	0	0	0	0
Not Completed*	5	6	12	6	3	1	4	37
Progressive disease	4	5	6	3	2	1	4	25
Physician Decision	1	0	3	2	1	0	0	7
Adverse Event	0	1	2	0	0	0	0	3
Patient decision	0	0	0	1	0	0	0	1
Technical problems	0	0	1	0	0	0	0	1

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

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Baseline Characteristics

	AML: VOB560 25mgQW + MIK665 25mgQW	AML: VOB560 25mgQW + MIK665 50mgQW	AML: VOB560 50mgQW + MIK665 25mgQW	AML: VOB560 50mgQW + MIK665 50mgQW	NHL and MM: VOB560 25mgQW + MIK665 25mgQW	NHL and MM: VOB560 25mgQW + MIK665 50mgQW	NHL and MM: VOB560 50mgQW + MIK665 25mgQW	Total
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	
Number of Participants [units: participants]	5	6	12	6	3	1	4	37
Baseline Analysis Population Description								
Age Continuous (units: years) Analysis Population Type: Mean ± Standard Deviation								
	64.8±14.96	54.7±12.52	61.8±13.46	60.7±23.81	58.3±28.11	55.0	61.0±12.68	60.3±15.75
Age, Customized (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)								
18 - < 65 years	2	5	6	3	1	1	2	20
65 - < 85 years	3	1	5	2	2	0	2	15
>= 85 years	0	0	1	1	0	0	0	2
Sex: Female, Male (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)								

Female	2	2	7	2	2	1	0	16
Male	3	4	5	4	1	0	4	21
Race/Ethnicity, Customized (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)								
Asian	1	2	4	1	0	0	1	9
White	4	4	8	5	3	1	3	28
Study Specific Characteristic Diagnosis of disease (units: participants) Analysis Population Type: Participants Count of Participants (Not Applicable)								
Acute myeloid leukemia	5	6	12	6	0	0	0	29
B Cell Non-Hodgkin Lymphoma	0	0	0	0	3	0	1	4
Plasma Cell Myeloma	0	0	0	0	0	1	3	4

Primary Outcome Result(s)

Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs)

Description	Number of participants with AEs (any AE regardless of seriousness) and SAEs, including changes from baseline in vital signs, electrocardiograms and laboratory results qualifying and reported as AEs.
Time Frame	From first dose of study treatment to 30 days after last dose, up to maximum 121 weeks (R/R AML) and 12 weeks (R/R NHL and R/R MM)
Analysis Population Description	All patients who received at least one dose of study treatment.

	AML: VOB560 25mgQW + MIK665 25mgQW	AML: VOB560 25mgQW + MIK665 50mgQW	AML: VOB560 50mgQW + MIK665 25mgQW	AML: VOB560 50mgQW + MIK665 50mgQW	NHL and MM: VOB560 25mgQW + MIK665 25mgQW	NHL and MM: VOB560 25mgQW + MIK665 50mgQW	NHL and MM: VOB560 50mgQW + MIK665 25mgQW
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	5	6	12	6	3	1	4
Number of participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
AEs	5 (100%)	6 (100%)	12 (100%)	5 (83.33%)	3 (100%)	1 (100%)	4 (100%)
Treatment-related AEs	5 (100%)	3 (50%)	7 (58.33%)	4 (66.67%)	1 (33.33%)	1 (100%)	2 (50%)
SAEs	2 (40%)	6 (100%)	7 (58.33%)	3 (50%)	0 (%)	0 (%)	0 (%)
Treatment-related SAEs	1 (20%)	1 (16.67%)	3 (25%)	1 (16.67%)	0 (%)	0 (%)	0 (%)
Fatal SAEs	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Treatment-related fatal SAEs	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Number of participants with Dose-Limiting Toxicities (DLTs) – Dose escalation only

Description A dose-limiting toxicity (DLT) is defined as an adverse event or abnormal laboratory value of Common Terminology Criteria for Adverse Events (CTCAE) grade ≥ 3 assessed as unrelated to disease, disease progression, inter-current illness, or concomitant medications that

occurs within the 21 days (first cycle) of treatment with VOB560 and/or MIK665. Other clinically significant toxicities could be considered to be DLTs, even if not CTCAE grade 3 or higher.

Time Frame: 21 days (Cycle 1)

Analysis Population Description: All patients who received at least one dose of study treatment during the dose escalation part, and who met the minimum exposure criterion defined in the protocol and had sufficient safety evaluations or experienced a DLT during Cycle 1.

	AML: VOB560 25mgQW + MIK665 25mgQW	**AML: VOB560 25mgQW + MIK665 50mgQW**	**AML: VOB560 50mgQW + MIK665 25mgQW**	**AML: VOB560 50mgQW + MIK665 50mgQW**	**NHL and MM: VOB560 25mgQW + MIK665 25mgQW**	**NHL and MM: VOB560 25mgQW + MIK665 50mgQW**	**NHL and MM: VOB560 50mgQW + MIK665 25mgQW**
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	4	6	11	5	3	1	4
Number of participants with Dose-Limiting Toxicities (DLTs) – Dose escalation only (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
At least one DLT	1 (25%)	1 (16.67%)	1 (9.09%)	2 (40%)	0 (%)	0 (%)	0 (%)
Differentiation syndrome	0 (%)	1 (16.67%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Ejection fraction decreased	0 (%)	0 (%)	0 (%)	1 (20%)	0 (%)	0 (%)	0 (%)
Muscle spasms	0 (%)	0 (%)	0 (%)	1 (20%)	0 (%)	0 (%)	0 (%)

Myopericarditis	1 (25%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Tumour lysis syndrome	0 (%)	0 (%)	1 (9.09%)	0 (%)	0 (%)	0 (%)	0 (%)

Number of participants with dose reductions and dose interruptions of VOB560

Description	Number of participants with at least one dose reduction and at least one dose interruption of VOB560. For patients who did not tolerate the protocol-specified dosing schedule, dose interruptions, and/or reductions were either recommended or mandated in order to allow patients to continue the study treatment.
Time Frame	From first dose of study treatment to last dose, up to maximum 117 weeks (R/R AML) and 8 weeks (R/R NHL and R/R MM)
Analysis Population Description	All patients who received at least one dose of VOB560

	AML: VOB560 25mgQW + MIK665 25mgQW	**AML: VOB560 25mgQW + MIK665 50mgQW**	**AML: VOB560 50mgQW + MIK665 25mgQW**	**AML: VOB560 50mgQW + MIK665 50mgQW**	**NHL and MM: VOB560 25mgQW + MIK665 25mgQW**	**NHL and MM: VOB560 25mgQW + MIK665 50mgQW**	**NHL and MM: VOB560 50mgQW + MIK665 25mgQW**
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	5	6	12	6	3	1	4
Number of participants with dose reductions and dose interruptions of VOB560 (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**

At least one dose reduction or interruption	1 (20%)	0 (%)	5 (41.67%)	2 (33.33%)	1 (33.33%)	0 (%)	1 (25%)
At least one dose reduction	0 (%)	0 (%)	2 (16.67%)	1 (16.67%)	0 (%)	0 (%)	0 (%)
At least one dose interruption	1 (20%)	0 (%)	4 (33.33%)	1 (16.67%)	1 (33.33%)	0 (%)	1 (25%)

Number of participants with dose reductions and dose interruptions of MIK665

Description	Number of participants with at least one dose reduction and at least one dose interruption of MIK665. For patients who did not tolerate the protocol-specified dosing schedule, dose interruptions, and/or reductions were either recommended or mandated in order to allow patients to continue the study treatment.
Time Frame	From first dose of study treatment to last dose, up to maximum 117 weeks (R/R AML) and 8 weeks (R/R NHL and R/R MM)
Analysis Population Description	All patients who received at least one dose of MIK665

	AML: VOB560 25mgQW + MIK665 25mgQW	**AML: VOB560 25mgQW + MIK665 50mgQW**	**AML: VOB560 50mgQW + MIK665 25mgQW**	**AML: VOB560 50mgQW + MIK665 50mgQW**	**NHL and MM: VOB560 25mgQW + MIK665 25mgQW**	**NHL and MM: VOB560 25mgQW + MIK665 50mgQW**	**NHL and MM: VOB560 50mgQW + MIK665 25mgQW**
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	5	6	12	6	3	1	4
Number of participants with dose reductions and dose interruptions of	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**

MIK665 (units: participants)							
At least one dose reduction or interruption	1 (20%)	0 (%)	4 (33.33%)	1 (16.67%)	1 (33.33%)	0 (%)	1 (25%)
At least one dose reduction	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
At least one dose interruption	1 (20%)	0 (%)	4 (33.33%)	1 (16.67%)	1 (33.33%)	0 (%)	1 (25%)

Dose intensity of VOB560

Description	Dose intensity of VOB560 was calculated as cumulative actual dose in milligrams divided by duration of exposure in weeks.
Time Frame	From first dose of study treatment to last dose, up to maximum 117 weeks (R/R AML) and 8 weeks (R/R NHL and R/R MM)
Analysis Population Description	All patients who received at least one dose of VOB560

	AML: VOB560 25mgQW + MIK665 25mgQW	**AML: VOB560 25mgQW + MIK665 50mgQW**	**AML: VOB560 50mgQW + MIK665 25mgQW**	**AML: VOB560 50mgQW + MIK665 50mgQW**	**NHL and MM: VOB560 25mgQW + MIK665 25mgQW**	**NHL and MM: VOB560 25mgQW + MIK665 50mgQW**	**NHL and MM: VOB560 50mgQW + MIK665 25mgQW**
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	5	6	12	6	3	1	4
Dose intensity of VOB560 (units: mg/week)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**

25.000 (18.10 to 25.00)	25.000 (25.00 to 25.00)	49.148 (33.33 to 50.00)	50.000 (45.65 to 50.00)	25.000 (23.75 to 25.00)	25.000 (25.00 to 25.00)	48.333 (41.67 to 50.00)

Dose intensity of MIK665

Description	Dose intensity of MIK665 was calculated as cumulative actual dose in milligrams divided by duration of exposure in weeks.
Time Frame	From first dose of study treatment to last dose, up to maximum 117 weeks (R/R AML) and 8 weeks (R/R NHL and R/R MM)
Analysis Population Description	All patients who received at least one dose of MIK665

	AML: VOB560 25mgQW + MIK665 25mgQW	**AML: VOB560 25mgQW + MIK665 50mgQW**	**AML: VOB560 50mgQW + MIK665 25mgQW**	**AML: VOB560 50mgQW + MIK665 50mgQW**	**NHL and MM: VOB560 25mgQW + MIK665 25mgQW**	**NHL and MM: VOB560 25mgQW + MIK665 50mgQW**	**NHL and MM: VOB560 50mgQW + MIK665 25mgQW**
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	5	6	12	6	3	1	4
Dose intensity of MIK665 (units: mg/week)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
	25.000 (18.10 to 25.00)	50.000 (50.00 to 50.00)	24.824 (19.44 to 25.00)	50.000 (45.65 to 50.00)	25.000 (21.88 to 25.00)	50.000 (50.00 to 50.00)	24.167 (20.83 to 25.00)

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Secondary Outcome Result(s)

Best Overall Response (BOR) per ELN 2017 for AML

Description	The best overall response (BOR) is the best response recorded from the start of the treatment until disease progression/recurrence. However, any assessments taken more than 30 days after the last dose of study therapy were not included in the best overall response derivation. Moreover, if any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination. Confirmed BOR was summarized by study treatment and disease indication. Efficacy was based on local investigator assessment per the European Leukemia Network (ELN) 2017 for AML.
Time Frame	Up to maximum 117 weeks
Analysis Population Description	All patients with R/R AML who received at least one dose of study treatment.

	AML: VOB560 25mgQW + MIK665 25mgQW	**AML: VOB560 25mgQW + MIK665 50mgQW**	**AML: VOB560 50mgQW + MIK665 25mgQW**	**AML: VOB560 50mgQW + MIK665 50mgQW**
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML
Number of Participants Analyzed [units: participants]	5	6	12	6
Best Overall Response (BOR) per ELN 2017 for AML (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
Complete Remission (CR)	0 (%)	0 (%)	2 (16.67%)	0 (%)
CR with incomplete hemotologic recovery (CRi)	0 (%)	0 (%)	0 (%)	0 (%)
Partial Remission (PR)	0 (%)	0 (%)	1 (8.33%)	0 (%)
Stable Disease (SD)	2 (40%)	0 (%)	5 (41.67%)	3 (50%)
Progressive Disease (PD)	1 (20%)	3 (50%)	1 (8.33%)	1 (16.67%)

Indeterminate response (IR)	0 (%)	1 (16.67%)	1 (8.33%)	0 (%)
Unknown (UNK)	2 (40%)	2 (33.33%)	2 (16.67%)	2 (33.33%)

Best Overall Response (BOR) per Lugano Classification criteria for lymphoma

Description	The best overall response (BOR) is the best response recorded from the start of the treatment until disease progression/recurrence. However, any assessments taken more than 30 days after the last dose of study therapy were not included in the best overall response derivation. Moreover, if any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination. Confirmed BOR was summarized by study treatment and disease indication. Efficacy was based on local investigator assessment per Lugano Classification criteria for lymphoma.
Time Frame	Up to maximum 8 weeks
Analysis Population Description	All patients with R/R NHL who received at least one dose of study treatment.

	NHL and MM: VOB560 25mgQW + MIK665 25mgQW	**NHL and MM: VOB560 25mgQW + MIK665 50mgQW**	**NHL and MM: VOB560 50mgQW + MIK665 25mgQW**
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	3	0	1
Best Overall Response (BOR) per Lugano Classification criteria for lymphoma (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
Complete Response (CR)	0 (%)	(NaN%)	0 (%)
Partial Response (PR)	0 (%)	(NaN%)	0 (%)
Stable Disease (SD)	1 (33.33%)	(NaN%)	0 (%)

Progressive Disease (PD)	1 (33.33%)	(NaN%)	1 (100%)
Unknown (UNK)	1 (33.33%)	(NaN%)	0 (%)

Best Overall Response (BOR) per IMWG criteria for MM

Description	The best overall response (BOR) is the best response recorded from the start of the treatment until disease progression/recurrence. However, any assessments taken more than 30 days after the last dose of study therapy were not included in the best overall response derivation. Moreover, if any alternative cancer therapy was taken while on study, any subsequent assessments were excluded from the best overall response determination. Confirmed BOR was summarized by study treatment and disease indication. Efficacy was based on local investigator assessment per the International Myeloma Working Group (IMWG) criteria for MM.
Time Frame	Up to maximum 8 weeks
Analysis Population Description	All patients with R/R MM who received at least one dose of study treatment.

	NHL and MM: VOB560 25mgQW + MIK665 25mgQW	**NHL and MM: VOB560 25mgQW + MIK665 50mgQW**	**NHL and MM: VOB560 50mgQW + MIK665 25mgQW**
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	0	1	3
Best Overall Response (BOR) per IMWG criteria for MM (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
Complete Response (CR)	(NaN%)	0 (%)	0 (%)
Partial Response (PR)	(NaN%)	0 (%)	0 (%)
Stable Disease (SD)	(NaN%)	0 (%)	0 (%)

Progressive Disease (PD)	(NaN%)	1 (100%)	3 (100%)
Unknown (UNK)	(NaN%)	0 (%)	0 (%)

Overall CR rate per ELN 2017 for AML

Description	Overall CR rate was defined as the percentage of patients who achieved complete remission (CR). Efficacy was based on local investigator assessment per the European Leukemia Network (ELN) 2017 for AML.
Time Frame	Up to maximum 117 weeks
Analysis Population Description	All patients with R/R AML who received at least one dose of study treatment.

	AML: VOB560 25mgQW + MIK665 25mgQW	**AML: VOB560 25mgQW + MIK665 50mgQW**	**AML: VOB560 50mgQW + MIK665 25mgQW**	**AML: VOB560 50mgQW + MIK665 50mgQW**
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML
Number of Participants Analyzed [units: participants]	5	6	12	6
Overall CR rate per ELN 2017 for AML (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
	0 (%)	0 (%)	2 (16.67%)	0 (%)

Overall CR rate per Lugano Classification criteria for lymphoma

Description	Overall CR rate was defined as the percentage of patients who achieved complete response (CR). Efficacy was based on local investigator assessment per Lugano Classification criteria for lymphoma.
Time Frame	Up to maximum 8 weeks

Analysis Population Description	All patients with R/R NHL who received at least one dose of study treatment.

	NHL and MM: VOB560 25mgQW + MIK665 25mgQW	NHL and MM: VOB560 25mgQW + MIK665 50mgQW	NHL and MM: VOB560 50mgQW + MIK665 25mgQW
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	3	0	1
Overall CR rate per Lugano Classification criteria for lymphoma (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
	0 (%)	(NaN%)	0 (%)

Overall CR rate per IMWG criteria for MM

Description	Overall CR rate was defined as the percentage of patients who achieved complete response (CR). Efficacy was based on local investigator assessment per the International Myeloma Working Group (IMWG) criteria for MM.
Time Frame	Up to maximum 8 weeks
Analysis Population Description	All patients with R/R MM who received at least one dose of study treatment.

	NHL and MM: VOB560 25mgQW + MIK665 25mgQW	NHL and MM: VOB560 25mgQW + MIK665 50mgQW	NHL and MM: VOB560 50mgQW + MIK665 25mgQW
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM

Number of Participants Analyzed [units: participants]	0	1	3
Overall CR rate per IMWG criteria for MM (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
	(NaN%)	0 (%)	0 (%)

Overall Response Rate (ORR) per ELN 2017 for AML

Description	ORR is the percentage of patients with a best overall response of complete response (CR), CR with incomplete hemotologic recovery (CRi) or partial response (PR). Efficacy was based on local investigator assessment per the European Leukemia Network (ELN) 2017 for AML.
Time Frame	Up to maximum 117 weeks
Analysis Population Description	All patients with R/R AML who received at least one dose of study treatment.

	AML: VOB560 25mgQW + MIK665 25mgQW	**AML: VOB560 25mgQW + MIK665 50mgQW**	**AML: VOB560 50mgQW + MIK665 25mgQW**	**AML: VOB560 50mgQW + MIK665 50mgQW**
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML
Number of Participants Analyzed [units: participants]	5	6	12	6
Overall Response Rate (ORR) per ELN 2017 for AML (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
	0 (%)	0 (%)	3 (25%)	0 (%)

Overall Response Rate (ORR) per Lugano Classification criteria for lymphoma

Description	ORR is the percentage of patients with a best overall response of complete response (CR) or partial response (PR). Efficacy was based on local investigator assessment per Lugano Classification criteria for lymphoma.

Time Frame	Up to maximum 8 weeks
Analysis Population Description	All patients with R/R NHL who received at least one dose of study treatment.

	NHL and MM: VOB560 25mgQW + MIK665 25mgQW	NHL and MM: VOB560 25mgQW + MIK665 50mgQW	NHL and MM: VOB560 50mgQW + MIK665 25mgQW
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	3	0	1
Overall Response Rate (ORR) per Lugano Classification criteria for lymphoma (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
	0 (%)	(NaN%)	0 (%)

Overall Response Rate (ORR) per IMWG criteria for MM

Description	ORR is the percentage of patients with a best overall response of complete response (CR) or partial response (PR). Efficacy was based on local investigator assessment per the International Myeloma Working Group (IMWG) criteria for MM.
Time Frame	Up to maximum 8 weeks
Analysis Population Description	All patients with R/R MM who received at least one dose of study treatment.

	NHL and MM: VOB560 25mgQW + MIK665 25mgQW	NHL and MM: VOB560 25mgQW + MIK665 50mgQW	NHL and MM: VOB560 50mgQW + MIK665 25mgQW
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM

Number of Participants Analyzed [units: participants]	0	1	3
Overall Response Rate (ORR) per IMWG criteria for MM (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
	(NaN%)	0 (%)	0 (%)

Duration of Response (DOR) per ELN 2017 for AML

Description	DOR only applied to patients whose best overall response was complete response (CR), CR with incomplete hemotologic recovery (CRi) or partial response (PR) based on local investigator assessment per ELN 2017 for AML. DOR is defined as the time between the date of first documented response (CR, CRi or PR) to the date of first documented disease progression (PD) or death due to any cause. DOR was analyzed using Kaplan-Meier estimates. DOR was summarized in any study treatment and indication with at least 7 responses.
Time Frame	Up to maximum 117 weeks
Analysis Population Description	All patients with R/R AML who received at least one dose of study treatment and were responders.

	AML: VOB560 25mgQW + MIK665 25mgQW	**AML: VOB560 25mgQW + MIK665 50mgQW**	**AML: VOB560 50mgQW + MIK665 25mgQW**	**AML: VOB560 50mgQW + MIK665 50mgQW**
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML
Number of Participants Analyzed [units: participants]	0	0	3	0
Duration of Response (DOR) per ELN 2017 for AML (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**
			NA (NA to NA)[1]	

[1] DOR could not be assessed because there were less than 7 responders.

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Duration of Response (DOR) per Lugano Classification criteria for lymphoma

Description	DOR only applied to patients whose best overall response was complete response (CR) or partial response (PR) based on local investigator assessment per Lugano Classification criteria for lymphoma. DOR is defined as the time between the date of first documented response (CR or PR) to the date of first documented disease progression (PD) or death due to any cause. DOR was analyzed using Kaplan-Meier estimates. DOR was summarized in any study treatment and indication with at least 7 responses.
Time Frame	Up to maximum 8 weeks
Analysis Population Description	All patients with R/R NHL who received at least one dose of study treatment and were responders.

	NHL and MM: VOB560 25mgQW + MIK665 25mgQW	**NHL and MM: VOB560 25mgQW + MIK665 50mgQW**	**NHL and MM: VOB560 50mgQW + MIK665 25mgQW**
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	0	0	0
Duration of Response (DOR) per Lugano Classification criteria for lymphoma (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**

Duration of Response (DOR) per IMWG criteria for MM

Description	DOR only applied to patients whose best overall response was complete response (CR) or partial response (PR) based on local investigator assessment per IMWG criteria for MM. DOR is defined as the time between the date of first documented response (CR or PR) to the date of first documented disease progression (PD) or death due to any cause.
Time Frame	Up to maximum 8 weeks
Analysis Population Description	All patients with R/R MM who received at least one dose of study treatment and were responders.

	NHL and MM: VOB560 25mgQW + MIK665 25mgQW	NHL and MM: VOB560 25mgQW + MIK665 50mgQW	NHL and MM: VOB560 50mgQW + MIK665 25mgQW
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	0	0	0
Duration of Response (DOR) per IMWG criteria for MM (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**

Progression-Free Survival (PFS) per ELN 2017 for AML

Description	Progression free survival is defined as the time from the date of start of treatment to the date of the first documented progression or relapse from CR or iCR or death due to any cause. PFS was assessed per local review according to ELN 2017 for AML. PFS was analyzed using Kaplan-Meier estimates. PFS was summarized in any study treatment and indication with at least 10 patients treated.
Time Frame	Up to maximum 121 weeks
Analysis Population Description	All patients with R/R AML who received at least one dose of study treatment.

	AML: VOB560 25mgQW + MIK665 25mgQW	AML: VOB560 25mgQW + MIK665 50mgQW	AML: VOB560 50mgQW + MIK665 25mgQW	AML: VOB560 50mgQW + MIK665 50mgQW
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML
Number of Participants Analyzed [units: participants]	5	6	12	6
Progression-Free Survival (PFS) per ELN 2017 for AML (units: months)	**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]	1.7 (1.4 to NA)[2]	NA (NA to NA)[1]

[1] PFS could not be assessed because there were less than 10 patients treated.
[2] Not estimable due to insufficient number of participants with events.

Progression-Free Survival (PFS) per Lugano Classification criteria for lymphoma

Description	Progression free survival is defined as the time from the date of start of treatment to the date of the first documented progression or death due to any cause. PFS was assessed per local review according to Lugano Classification criteria for lymphoma. PFS was analyzed using Kaplan-Meier estimates. PFS was summarized in any study treatment and indication with at least 10 patients treated.
Time Frame	Up to maximum 12 weeks
Analysis Population Description	All patients with R/R NHL who received at least one dose of study treatment.

	NHL and MM: VOB560 25mgQW + MIK665 25mgQW	**NHL and MM: VOB560 25mgQW + MIK665 50mgQW**	**NHL and MM: VOB560 50mgQW + MIK665 25mgQW**
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	3	0	1
Progression-Free Survival (PFS) per Lugano Classification criteria for lymphoma (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**
	NA (NA to NA)[1]		NA (NA to NA)[1]

[1] PFS could not be assessed because there were less than 10 patients treated.

Progression-Free Survival (PFS) per IMWG criteria for MM

Description	Progression free survival is defined as the time from the date of start of treatment to the date of the first documented progression or death due to any cause. PFS was assessed per local review according to IMWG criteria for MM. PFS was analyzed using Kaplan-Meier estimates. PFS was summarized in any study treatment and indication with at least 10 patients treated.

Time Frame	Up to maximum 12 weeks
Analysis Population Description	All patients with R/R MM who received at least one dose of study treatment.

	NHL and MM: VOB560 25mgQW + MIK665 25mgQW	NHL and MM: VOB560 25mgQW + MIK665 50mgQW	NHL and MM: VOB560 50mgQW + MIK665 25mgQW
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	0	1	3
Progression-Free Survival (PFS) per IMWG criteria for MM (units: months)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**
		NA (NA to NA)[1]	NA (NA to NA)[1]

[1] PFS could not be assessed because there were less than 10 patients treated.

Maximum observed plasma concentration (Cmax) of VOB560

Description	Pharmacokinetic (PK) parameters were calculated based on VOB560 plasma concentrations by using non-compartmental methods. Cmax is defined as the maximum (peak) observed concentration following a dose, corresponding to the concentration at the end of the infusion. All PK time points listed were related to VOB560 treatment (1st drug to be infused in the combination treatment with MIK665).
Time Frame	pre-dose, 0.5, 1, 1.5, 2, 3, 4.5, 8, 12 and 24 hours post end of VOB560 infusion on Cycle 1 Day 1 (C1D1) and Cycle 1 Day 8 (C1D8). The duration of one cycle was 21 days.
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who received VOB560 and had an available value for the outcome measure at the corresponding timepoint.

	AML: VOB560 25mgQW +	AML: VOB560 25mgQW +	AML: VOB560 50mgQW +	AML: VOB560 50mgQW +	NHL and MM: VOB560 25mgQW +	NHL and MM: VOB560 25mgQW +	NHL and MM: VOB560 50mgQW +

	MIK665 25mgQW	MIK665 50mgQW	MIK665 25mgQW	MIK665 50mgQW	MIK665 25mgQW	MIK665 50mgQW	MIK665 25mgQW
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	5	6	11	5	3	1	3
Maximum observed plasma concentration (Cmax) of VOB560 (units: ng/mL)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
Cycle 1 Day 1 (n=4,6,11,5,3,1,3)	2260 (1140 to 3380)	1510 (667 to 2360)	2340 (1010 to 4890)	3430 (2490 to 27200)	2830 (1460 to 4630)	2940 (2940 to 2940)	3350 (2580 to 3790)
Cycle 1 Day 8 (n=2,5,11,4,2,1,3)	732 (505 to 958)	1820 (781 to 17100)	2610 (640 to 37300)	3210 (1420 to 5920)	1760 (1080 to 2430)	2500 (2500 to 2500)	3430 (3040 to 4510)

Area under the plasma concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of VOB560

Description	PK parameters were calculated based on VOB560 plasma concentrations by using non-compartmental methods. The linear trapezoidal method was used for AUC calculation. All PK time points listed were related to VOB560 treatment (1st drug to be infused in the combination treatment with MIK665).
Time Frame	pre-dose, 0.5, 1, 1.5, 2, 3, 4.5, 8, 12 and 24 hours post end of VOB560 infusion on Cycle 1 Day 1 (C1D1) and Cycle 1 Day 8 (C1D8). The duration of one cycle was 21 days.
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who received VOB560 and had an available value for the outcome measure at the corresponding timepoint.

	AML: VOB560 25mgQW +	AML: VOB560 25mgQW +	AML: VOB560 50mgQW +	AML: VOB560 50mgQW +	NHL and MM: VOB560	NHL and MM: VOB560	NHL and MM: VOB560

	MIK665 25mgQW	MIK665 50mgQW	MIK665 25mgQW	MIK665 50mgQW	25mgQW + MIK665 25mgQW	25mgQW + MIK665 50mgQW	50mgQW + MIK665 25mgQW
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	5	6	11	5	3	1	3
Area under the plasma concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of VOB560 (units: h*ng/mL)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
Cycle 1 Day 1 (n=4,6,11,5,3,1,3)	1670 (1130 to 3140)	1080 (838 to 1940)	2150 (844 to 4450)	3250 (1720 to 14100)	2210 (1290 to 3870)	3910 (3910 to 3910)	4020 (2570 to 5080)
Cycle 1 Day 8 (n=2,5,11,4,2,1,3)	653 (489 to 818)	1290 (602 to 8880)	2570 (526 to 19800)	2890 (1190 to 6240)	1470 (992 to 1950)	3680 (3680 to 3680)	4890 (2680 to 5400)

Terminal elimination half-life (T1/2) of VOB560

Description	PK parameters were calculated based on VOB560 plasma concentrations by using non-compartmental methods. T1/2 values were calculated as 0.693/terminal elimination rate constant. All PK time points listed were related to VOB560 treatment (1st drug to be infused in the combination treatment with MIK665).
Time Frame	pre-dose, 0.5, 1, 1.5, 2, 3, 4.5, 8, 12 and 24 hours post end of VOB560 infusion on Cycle 1 Day 1 (C1D1) and Cycle 1 Day 8 (C1D8). The duration of one cycle was 21 days.
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who received VOB560 and had an available value for the outcome measure at the corresponding timepoint.

	AML: VOB560 25mgQW + MIK665 25mgQW	AML: VOB560 25mgQW + MIK665 50mgQW	AML: VOB560 50mgQW + MIK665 25mgQW	AML: VOB560 50mgQW + MIK665 50mgQW	NHL and MM: VOB560 25mgQW + MIK665 25mgQW	NHL and MM: VOB560 25mgQW + MIK665 50mgQW	NHL and MM: VOB560 50mgQW + MIK665 25mgQW
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	5	6	11	5	3	1	3
Terminal elimination half-life (T1/2) of VOB560 (units: hours)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
Cycle 1 Day 1 (n=3,6,10,5,3,0,3)	2.79 (1.91 to 3.17)	1.34 (0.991 to 3.09)	2.36 (1.53 to 14.3)	2.39 (1.71 to 15.2)	2.95 (1.84 to 3.28)		4.5 (2.63 to 7.03)
Cycle 1 Day 8 (n=2,5,9,3,1,1,3)	1.9 (1.79 to 2.01)	2.32 (0.823 to 4.99)	2.58 (1.98 to 12.8)	2.7 (2.66 to 3.25)	2.48 (2.48 to 2.48)	5.68 (5.68 to 5.68)	5.36 (2.78 to 6.13)

Plasma clearance at steady state (CLss) of VOB560

Description	PK parameters were calculated based on VOB560 plasma concentrations by using non-compartmental methods. CLss values were calculated as Dose/AUCinf. All PK time points listed were related to VOB560 treatment (1st drug to be infused in the combination treatment with MIK665).
Time Frame	pre-dose, 0.5, 1, 1.5, 2, 3, 4.5, 8, 12 and 24 hours post end of VOB560 infusion on Cycle 1 Day 8 (C1D8). The duration of one cycle was 21 days.
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who received VOB560 and had an available value for the outcome measure at the corresponding timepoint.

	AML: VOB560 25mgQW +	AML: VOB560 25mgQW +	AML: VOB560 50mgQW +	AML: VOB560 50mgQW +	NHL and MM: VOB560	NHL and MM: VOB560	NHL and MM: VOB560

	MIK665 25mgQW	MIK665 50mgQW	MIK665 25mgQW	MIK665 50mgQW	25mgQW + MIK665 25mgQW	25mgQW + MIK665 50mgQW	50mgQW + MIK665 25mgQW
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	2	5	9	3	1	1	3
Plasma clearance at steady state (CLss) of VOB560 (units: mL/h)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
Cycle 1 Day 8 (n=2,5,9,3,1,1,3)	39800 (30000 to 49600)	19100 (2810 to 39300)	18900 (1870 to 92200)	19300 (7870 to 41000)	12200 (12200 to 12200)	6640 (6640 to 6640)	10100 (8940 to 18000)

Maximum observed plasma concentration (Cmax) of MIK665

Description	PK parameters were calculated based on MIK665 plasma concentrations by using non-compartmental methods. Cmax is defined as the maximum (peak) observed concentration following a dose, corresponding to the concentration at the end of the infusion. All PK time points listed were related to VOB560 treatment (1st drug to be infused in the combination treatment with MIK665).
Time Frame	pre-dose, 0.5, 1, 1.5, 2, 3, 4.5, 8, 12 and 24 hours post end of VOB560 infusion on Cycle 1 Day 1 (C1D1) and Cycle 1 Day 8 (C1D8). The duration of one cycle was 21 days.
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who received MIK665 and had an available value for the outcome measure at the corresponding timepoint.

	AML: VOB560 25mgQW + MIK665 25mgQW	AML: VOB560 25mgQW + MIK665 50mgQW	AML: VOB560 50mgQW + MIK665 25mgQW	AML: VOB560 50mgQW + MIK665 50mgQW	NHL and MM: VOB560 25mgQW + MIK665 25mgQW	NHL and MM: VOB560 25mgQW + MIK665 50mgQW	NHL and MM: VOB560 50mgQW + MIK665 25mgQW

Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	5	6	11	5	3	1	3
Maximum observed plasma concentration (Cmax) of MIK665 (units: ng/mL)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
Cycle 1 Day 1 (n=5,6,11,4,3,1,3)	920 (375 to 1870)	1790 (1.02 to 2500)	1140 (232 to 2230)	3910 (2010 to 6690)	606 (591 to 1880)	4070 (4070 to 4070)	1740 (787 to 3230)
Cycle 1 Day 8 (n=2,6,11,4,2,1,3)	2460 (800 to 4110)	2530 (1280 to 63200)	1480 (467 to 70300)	3120 (2240 to 3750)	850 (650 to 1050)	6140 (6140 to 6140)	2130 (487 to 2330)

Area under the plasma concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of MIK665

Description	PK parameters were calculated based on MIK665 plasma concentrations by using non-compartmental methods. The linear trapezoidal method was used for AUC calculation. All PK time points listed were related to VOB560 treatment (1st drug to be infused in the combination treatment with MIK665).
Time Frame	pre-dose, 0.5, 1, 1.5, 2, 3, 4.5, 8, 12 and 24 hours post end of VOB560 infusion on Cycle 1 Day 1 (C1D1) and Cycle 1 Day 8 (C1D8). The duration of one cycle was 21 days.
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who received MIK665 and had an available value for the outcome measure at the corresponding timepoint.

	AML: VOB560 25mgQW + MIK665 25mgQW	**AML: VOB560 25mgQW + MIK665 50mgQW**	**AML: VOB560 50mgQW + MIK665 25mgQW**	**AML: VOB560 50mgQW + MIK665 50mgQW**	**NHL and MM: VOB560 25mgQW +**	**NHL and MM: VOB560 25mgQW +**	**NHL and MM: VOB560 50mgQW +**

					MIK665 25mgQW	MIK665 50mgQW	MIK665 25mgQW
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	5	6	11	5	3	1	3
Area under the plasma concentration-time curve from time zero to the time of the last quantifiable concentration (AUClast) of MIK665 (units: h*ng/mL)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
Cycle 1 Day 1 (n=5,6,11,4,3,1,3)	524 (225 to 1800)	1060 (9.4 to 1410)	723 (272 to 1400)	1980 (1260 to 3830)	621 (357 to 1300)	2370 (2370 to 2370)	977 (449 to 1780)
Cycle 1 Day 8 (n=2,6,11,4,2,1,3)	1150 (419 to 1870)	1420 (780 to 69900)	935 (289 to 38500)	1810 (1310 to 2250)	1020 (746 to 1290)	3780 (3780 to 3780)	1350 (269 to 1470)

Terminal elimination half-life (T1/2) of MIK665

Description	PK parameters were calculated based on MIK665 plasma concentrations by using non-compartmental methods. T1/2 values were calculated as 0.693/terminal elimination rate constant. All PK time points listed were related to VOB560 treatment (1st drug to be infused in the combination treatment with MIK665).
Time Frame	pre-dose, 0.5, 1, 1.5, 2, 3, 4.5, 8, 12 and 24 hours post end of VOB560 infusion on Cycle 1 Day 1 (C1D1) and Cycle 1 Day 8 (C1D8). The duration of one cycle was 21 days.
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who received MIK665 and had an available value for the outcome measure at the corresponding timepoint.

	AML: VOB560 25mgQW +	AML: VOB560 25mgQW +	AML: VOB560 50mgQW +	AML: VOB560 50mgQW +	NHL and MM: VOB560	NHL and MM: VOB560	NHL and MM: VOB560

	MIK665 25mgQW	MIK665 50mgQW	MIK665 25mgQW	MIK665 50mgQW	25mgQW + MIK665 25mgQW	25mgQW + MIK665 50mgQW	50mgQW + MIK665 25mgQW
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	5	6	11	5	3	1	3
Terminal elimination half-life (T1/2) of MIK665 (units: hours)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
Cycle 1 Day 1 (n=5,4,9,2,2,1,3)	0.709 (0.507 to 5.13)	2.53 (1.72 to 3.57)	1.56 (0.871 to 2.67)	4.64 (2.46 to 6.83)	3.9 (2.97 to 4.83)	4.01 (4.01 to 4.01)	1.33 (1.24 to 2.35)
Cycle 1 Day 8 (n=2,5,9,4,0,1,3)	4.05 (0.62 to 7.49)	2.32 (1.28 to 5.22)	1.79 (0.912 to 3.27)	5.83 (2.24 to 10.4)		7.05 (7.05 to 7.05)	2.4 (1.24 to 2.93)

Plasma clearance at steady state (CLss) of MIK665

Description	PK parameters were calculated based on MIK665 plasma concentrations by using non-compartmental methods. CLss values were calculated as Dose/AUCinf. All PK time points listed were related to VOB560 treatment (1st drug to be infused in the combination treatment with MIK665).
Time Frame	pre-dose, 0.5, 1, 1.5, 2, 3, 4.5, 8, 12 and 24 hours post end of VOB560 infusion on Cycle 1 Day 8 (C1D8). The duration of one cycle was 21 days.
Analysis Population Description	Patients in the pharmacokinetic analysis set (PAS) who received MIK665 and had an available value for the outcome measure at the corresponding timepoint.

	AML: VOB560 25mgQW + MIK665 25mgQW	AML: VOB560 25mgQW + MIK665 50mgQW	AML: VOB560 50mgQW + MIK665 25mgQW	AML: VOB560 50mgQW + MIK665 50mgQW	NHL and MM: VOB560 25mgQW +	NHL and MM: VOB560 25mgQW +	NHL and MM: VOB560 50mgQW +

					MIK665 25mgQW	MIK665 50mgQW	MIK665 25mgQW
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	2	5	9	4	0	1	3
Plasma clearance at steady state (CLss) of MIK665 (units: mL/h)	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**	**Median (Full Range)**
Cycle 1 Day 8 (n=2,5,9,4,0,1,3)	36400 (13300 to 59400)	17100 (715 to 47300)	23100 (649 to 51600)	27500 (22200 to 37900)		13200 (13200 to 13200)	18400 (16900 to 92400)

Post-Hoc Outcome Result(s)

All-Collected Deaths

Description	On-treatment deaths were collected from first dose of study treatment to 30 days after last dose. Post-treatment deaths were collected from 31 days after last dose until end of study. All deaths refer to the sum of on-treatment and post-treatment deaths.
Time Frame	On-treatment deaths: up to approximately 121 weeks (R/R AML) and 12 weeks (R/R NHL and R/R MM). Post-treatment deaths: up to approximately 121 weeks (R/R AML) and 12 weeks (R/R NHL and R/R MM).
Analysis Population Description	All patients who received at least one dose of study treatment.

	AML: VOB560 25mgQW + MIK665 25mgQW	AML: VOB560 25mgQW + MIK665 50mgQW	AML: VOB560 50mgQW + MIK665 25mgQW	AML: VOB560 50mgQW + MIK665 50mgQW	NHL and MM: VOB560 25mgQW +	NHL and MM: VOB560 25mgQW +	NHL and MM: VOB560 50mgQW +

					MIK665 25mgQW	MIK665 50mgQW	MIK665 25mgQW
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Number of Participants Analyzed [units: participants]	5	6	12	6	3	1	4
All-Collected Deaths (units: participants)							
On-treatment deaths (n=5,6,12,6,3,1,4)	1	3	1	0	0	0	0
Post-treatment deaths (n=4,3,11,6,3,1,4)	1	0	2	0	0	0	0
All deaths (n=5,6,12,6,3,1,4)	2	3	3	0	0	0	0

Safety Results

Time Frame	Adverse events: from the first dose of study drug to 30 days after last dose, up to approximately 121 weeks (R/R AML) and 12 weeks (R/R NHL and R/R MM). All deaths: from the first dose of study treatment until end of study, up to approximately 121 weeks.
Source Vocabulary for Table Default	MedDRA (27.0)
Collection Approach for Table Default	Systematic Assessment

All-Cause Mortality

	AML: VOB560 25mgQW + MIK665 25mgQW N = 5	AML: VOB560 25mgQW + MIK665 50mgQW N = 6	AML: VOB560 50mgQW + MIK665 25mgQW N = 12	AML: VOB560 50mgQW + MIK665 50mgQW N = 6	NHL and MM: VOB560 25mgQW + MIK665 25mgQW N = 3	NHL and MM: VOB560 25mgQW + MIK665 50mgQW N = 1	NHL and MM: VOB560 50mgQW + MIK665 25mgQW N = 4
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Total Number Affected	2	3	3	0	0	0	0
Total Number At Risk	5	6	12	6	3	1	4

Serious Adverse Events

Time Frame	Adverse events: from the first dose of study drug to 30 days after last dose, up to approximately 121 weeks (R/R AML) and 12 weeks (R/R NHL and R/R MM). All deaths: from the first dose of study treatment until end of study, up to approximately 121 weeks.
Source Vocabulary for Table Default	MedDRA (27.0)
Collection Approach for Table Default	Systematic Assessment

	AML: VOB560 25mgQW + MIK665	AML: VOB560 25mgQW + MIK665	AML: VOB560 50mgQW + MIK665	AML: VOB560 50mgQW + MIK665	NHL and MM: VOB560 25mgQW + MIK665	NHL and MM: VOB560 25mgQW + MIK665	NHL and MM: VOB560 50mgQW + MIK665

	25mgQW N = 5	50mgQW N = 6	25mgQW N = 12	50mgQW N = 6	25mgQW N = 3	50mgQW N = 1	25mgQW N = 4
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM	VOB560 25 mg QD + MIK665 50 mg QD in R/R NHL and R/R MM	VOB560 50 mg QD + MIK665 25 mg QD in R/R NHL and R/R MM
Total # Affected by any Serious Adverse Event	2	6	7	3	0	0	0
Total # at Risk by any Serious Adverse Event	5	6	12	6	3	1	4
Blood and lymphatic system disorders							
Febrile neutropenia	0 (0.00%)	2 (33.33%)	1 (8.33%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukocytosis	1 (20.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac disorders							
Myopericarditis	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders							
Diarrhoea	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oesophagitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
General disorders and administration site conditions							
Pyrexia	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infections and infestations							
Bronchopulmonary aspergillosis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
COVID-19	0 (0.00%)	0 (0.00%)	3 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemophilus bacteraemia	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Lip infection	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lower respiratory tract infection fungal	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mastoiditis	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral herpes	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia	0 (0.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory syncytial virus infection	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory tract infection	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sepsis	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Staphylococcal infection	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metabolism and nutrition disorders							
Hyperphosphataemia	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour lysis syndrome	0 (0.00%)	0 (0.00%)	2 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal and connective tissue disorders							
Back pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Flank pain	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscle spasms	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Differentiation syndrome	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour associated fever	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory, thoracic and mediastinal disorders							
Hypoxia	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Vascular disorders							
Hypotension	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Other (Not Including Serious) Adverse Events

Time Frame	Adverse events: from the first dose of study drug to 30 days after last dose, up to approximately 121 weeks (R/R AML) and 12 weeks (R/R NHL and R/R MM). All deaths: from the first dose of study treatment until end of study, up to approximately 121 weeks.
Source Vocabulary for Table Default	MedDRA (27.0)
Collection Approach for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	5%

	AML: VOB560 25mgQW + MIK665 25mgQW N = 5	**AML: VOB560 25mgQW + MIK665 50mgQW N = 6**	**AML: VOB560 50mgQW + MIK665 25mgQW N = 12**	**AML: VOB560 50mgQW + MIK665 50mgQW N = 6**	**NHL and MM: VOB560 25mgQW + MIK665 25mgQW N = 3**	**NHL and MM: VOB560 25mgQW + MIK665 50mgQW N = 1**	**NHL and MM: VOB560 50mgQW + MIK665 25mgQW N = 4**
Arm/Group Description	VOB560 25 mg QD + MIK665 25 mg QD in R/R AML	VOB560 25 mg QD + MIK665 50 mg QD in R/R AML	VOB560 50 mg QD + MIK665 25 mg QD in R/R AML	VOB560 50 mg QD + MIK665 50 mg QD in R/R AML	VOB560 25 mg QD + MIK665 25 mg QD in	VOB560 25 mg QD + MIK665 50 mg QD in	VOB560 50 mg QD + MIK665 25 mg QD in

					R/R NHL and R/R MM	R/R NHL and R/R MM	R/R NHL and R/R MM
Total # Affected by any Other Adverse Event	5	6	11	5	3	1	4
Total # at Risk by any Other Adverse Event	5	6	12	6	3	1	4
Blood and lymphatic system disorders							
Anaemia	1 (20.00%)	1 (16.67%)	1 (8.33%)	0 (0.00%)	2 (66.67%)	0 (0.00%)	2 (50.00%)
Febrile neutropenia	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukocytosis	0 (0.00%)	2 (33.33%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neutropenia	2 (40.00%)	0 (0.00%)	2 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Thrombocytopenia	1 (20.00%)	0 (0.00%)	2 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac disorders							
Arteriospasm coronary	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Left ventricular failure	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Myopericarditis	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinus tachycardia	0 (0.00%)	1 (16.67%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ventricular extrasystoles	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye disorders							
Blepharitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Retinal haemorrhage	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders							
Abdominal discomfort	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal pain	1 (20.00%)	1 (16.67%)	1 (8.33%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Anal ulcer	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Aphthous ulcer	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Constipation	1 (20.00%)	0 (0.00%)	2 (16.67%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Diarrhoea	3 (60.00%)	2 (33.33%)	3 (25.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspepsia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastritis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrooesophageal reflux disease	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gingival bleeding	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mouth ulceration	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nausea	1 (20.00%)	3 (50.00%)	4 (33.33%)	2 (33.33%)	0 (0.00%)	1 (100.00%)	1 (25.00%)
Oesophagitis	0 (0.00%)	0 (0.00%)	2 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Toothache	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vomiting	1 (20.00%)	1 (16.67%)	3 (25.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
General disorders and administration site conditions							
Asthenia	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Chest pain	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chills	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fatigue	1 (20.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
General physical health deterioration	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Generalised oedema	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Mucosal inflammation	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oedema peripheral	0 (0.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pain	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pyrexia	2 (40.00%)	4 (66.67%)	2 (16.67%)	1 (16.67%)	1 (33.33%)	0 (0.00%)	1 (25.00%)

Swelling	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatobiliary disorders							
Cholelithiasis	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gallbladder polyp	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatic function abnormal	1 (20.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatomegaly	0 (0.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infections and infestations							
Cellulitis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Clostridium difficile infection	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
COVID-19	0 (0.00%)	0 (0.00%)	2 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Escherichia infection	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Escherichia sepsis	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Klebsiella sepsis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nasopharyngitis	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Norovirus infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral herpes	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia	0 (0.00%)	1 (16.67%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pustule	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinitis	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sepsis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Septic shock	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinusitis	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Trichosporon infection	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Upper respiratory tract infection	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary tract infection	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injury, poisoning and procedural complications							
Anastomotic ulcer	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fall	1 (20.00%)	2 (33.33%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hand fracture	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infusion related reaction	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Joint injury	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Limb injury	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Investigations							
Alanine aminotransferase increased	0 (0.00%)	0 (0.00%)	2 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Aspartate aminotransferase increased	0 (0.00%)	2 (33.33%)	3 (25.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood alkaline phosphatase increased	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Blood creatine phosphokinase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)
Blood creatinine increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)
Blood fibrinogen increased	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood lactate dehydrogenase increased	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)
Blood phosphorus increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)
Blood thyroid stimulating hormone increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)

Blood urea increased	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Brain natriuretic peptide increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)
Cardiac murmur	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
C-reactive protein increased	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ejection fraction decreased	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fibrin D dimer increased	0 (0.00%)	1 (16.67%)	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 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
N-terminal prohormone brain natriuretic peptide increased	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oxygen saturation decreased	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Platelet count decreased	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Troponin I increased	0 (0.00%)	1 (16.67%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Troponin increased	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Troponin T increased	2 (40.00%)	1 (16.67%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Weight decreased	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Weight increased	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
White blood cell count decreased	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Metabolism and nutrition disorders							
Dehydration	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fluid retention	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperkalaemia	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypermagnesaemia	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Hyperphosphataemia	0 (0.00%)	1 (16.67%)	2 (16.67%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)
Hyperuricaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Hypoalbuminaemia	0 (0.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypocalcaemia	0 (0.00%)	2 (33.33%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypochloraemia	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypokalaemia	2 (40.00%)	2 (33.33%)	4 (33.33%)	3 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypomagnesaemia	1 (20.00%)	1 (16.67%)	1 (8.33%)	2 (33.33%)	1 (33.33%)	0 (0.00%)	0 (0.00%)
Hyponatraemia	0 (0.00%)	3 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypophosphataemia	2 (40.00%)	2 (33.33%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypoproteinaemia	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour lysis syndrome	0 (0.00%)	0 (0.00%)	2 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal and connective tissue disorders							
Arthralgia	1 (20.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Back pain	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bone pain	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)
Flank pain	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscle spasms	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscular weakness	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Myalgia	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neck pain	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)
Pain in extremity	0 (0.00%)	1 (16.67%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Periarthritis	2 (40.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							

Differentiation syndrome	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukaemia cutis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour associated fever	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tumour pain	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nervous system disorders							
Dizziness	1 (20.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dizziness postural	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Headache	1 (20.00%)	1 (16.67%)	4 (33.33%)	2 (33.33%)	1 (33.33%)	0 (0.00%)	0 (0.00%)
Paraesthesia	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Presyncope	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Psychiatric disorders							
Dysphoria	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Insomnia	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal and urinary disorders							
Dysuria	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal cyst	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary retention	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Reproductive system and breast disorders							
Pelvic pain	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory, thoracic and mediastinal disorders							
Cough	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dyspnoea	0 (0.00%)	1 (16.67%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Epistaxis	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Haemoptysis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Haemothorax	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypoxia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lung infiltration	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oropharyngeal pain	1 (20.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tachypnoea	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin and subcutaneous tissue disorders							
Acute febrile neutrophilic dermatosis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blister	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Decubitus ulcer	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Erythema multiforme	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hyperhidrosis	0 (0.00%)	1 (16.67%)	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%)	1 (33.33%)	0 (0.00%)	0 (0.00%)
Petechiae	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pruritus	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urticaria	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vascular disorders							
Hypertension	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypotension	0 (0.00%)	1 (16.67%)	2 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ischaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Thrombophlebitis	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Conclusion:

Overall, the study provides valuable insights into the PK, efficacy and safety of the combination treatment for R/R AML, NHL, and MM, and the combination treatment was found to be safe and tolerable for R/R AML, NHL, and MM.

Date of Clinical Trial Report

22-Apr-2025