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Sponsor

Novartis Pharmaceuticals

Generic Drug Name

Sabatolimab

Trial Indication(s)

Myelodysplastic syndrome

Protocol Number

CMBG453B12203

Protocol Title

A single-arm, open-label, phase II study of sabatolimab in combination with azacitidine and venetoclax in adult participants with high or very high risk myelodysplastic syndromes (MDS) as per IPSS-R criteria

Clinical Trial Phase

Phase 2

Phase of Drug Development

Phase III

Study Start/End Dates

Study Start Date: May 31, 2021 (Actual)
Primary Completion Date: May 08, 2023 (Actual)
Study Completion Date: May 08, 2023 (Actual)

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Reason for Termination (If applicable)

Novartis made the decision to permanently halt recruitment of new participants into this study. The decision was based on a reevaluation of the development strategy for sabatolimab and not based on any safety findings or safety concerns with sabatolimab, either in combination with an Hypomethylating agents (HMA) or as part of this triplet combination; consequently, the Expansion phase (Part 2) of the study did not open.

Study Design/Methodology

This was a Phase II, open-label, single-arm, multi-center study of sabatolimab in combination with azacitidine and venetoclax in adult participants with high or very high risk MDS as per IPSS-R criteria. Due to the decision by Novartis to halt recruitment at the end of the Safety run-in, the study did not enroll the approximately 76 participants that were planned. The study enrolled participants in Part 1 only.

- Part 1: Safety run-in consisted of two subsequent cohorts of 400 mg Q4W (Cohort 1) and 800 mg Q4W (Cohort 2) of sabatolimab in combination with fixed dose of venetoclax and azacitidine. Cohort 2 was to be opened only after the review of safety data from Cohort 1 indicated the regimen was safe. If the regimen using sabatolimab at 400 mg Q4W was not safe, the study was to be stopped. Subsequently, if the review of safety data from participants enrolled in Cohort 2 indicated the regimen was safe, then Part 2 was to be opened. Otherwise, if the regimen at 800 mg Q4W was not safe, the study was to be stopped.
- Part 2: Expansion, which did not open, was to enroll additional participants to further investigate the regimen including sabatolimab at 800 mg Q4W, azacitidine and venetoclax. Participants data from Part 1 and Part 2 treated with 800 mg Q4W were to be combined to determine the complete remission rate.

Part 1 was a Safety run-in to assess whether sabatolimab (400 mg Q4W and subsequently 800 mg Q4W) is safe when given in combination with a fixed dose of azacitidine and venetoclax. Approximately 18 participants were to be enrolled in Part 1 across the two dose levels. Approximately 6 participants were to be initially enrolled at the starting dose level, 400 mg Q4W (Cohort 1), in order to obtain at least 3 evaluable participants for evaluability criteria. If the dose level of sabatolimab 400 mg Q4W in combination with azacitidine and venetoclax was assessed to be safe, then a second cohort of participants investigating sabatolimab at 800 mg Q4W combined to azacitidine and venetoclax (Cohort 2) was to be opened. Otherwise, the study would be stopped.

Approximately 12 participants were to be enrolled in Cohort 2, in order to obtain at least 9 evaluable participants for evaluability criteria. If the combination regimen used in Cohort 2 were safe, then the Expansion part was to be opened (Part 2). Otherwise the study would be stopped. For each dose level, once the required number of evaluable participants was confirmed, enrollment was to be halted until participants had completed the DLT observation period, and a Safety Review Meeting had been conducted.

If no safety concerns were identified at either dose level enrollment into Part 2 was to continue until approximately 70 participants were treated at the sabatolimab dose of 800 mg Q4W (including the participants treated in Cohort 2 in the Safety run-in (Part 1), and participants treated in the Expansion (Part 2)) had been achieved. Since Novartis made the decision to permanently halt recruitment at the end of Part 1, the Expansion (Part 2) did not open.

Centers

10 centers in 7 countries: Belgium(1), France(2), Hungary(1), Greece(2), Spain(1), Germany(2), Italy(1)

Objectives:

The primary objectives and related endpoints were:

Safety run-in (Cohort 1 and Cohort 2 of Part 1):

To determine whether sabatolimab is safe when added to azacitidine + venetoclax in participants with high or very high risk MDS per IPSS-R criteria

Cohort 2 of Safety run-in (Part 1) and Expansion (Part 2):

- To determine the complete remission (CR) rate of sabatolimab in combination with azacitidine and venetoclax in participants with high or very high risk MDS as per IPSS-R criteria treated with sabatolimab at 800 mg Q4W.

The secondary objectives and endpoints were:

Safety run-in (Part 1) and Expansion (Part 2):

- To assess the [CR + marrow complete remission (mCR)] rate
- To assess Overall Response Rate (ORR), per modified IWG-MDS Cheson 2006 criteria, defined as the proportion of participants achieving [CR + mCR + partial remission (PR) + hematologic improvement (HI)]
- To assess the improvement in RBC/platelets transfusion independence
- To characterize the safety profile of sabatolimab when administered in combination with azacitidine and venetoclax

- To further characterize the pharmacokinetics of sabatolimab when administered in combination with azacitidine and venetoclax
- To characterize the immunogenicity of sabatolimab when given in combination with venetoclax and azacitidine

Cohort 2 of Safety run-in (Part 1) and Expansion (Part 2):

- To assess the duration of CR
- To assess the time to CR/mCR
- To assess the duration of CR/Mcr
- To assess duration of response (responding participants defined as hematological improvement (HI) or better, per modified IWG-MDS Cheson 2006 criteria) as per investigator assessment.
- To assess Progression-Free Survival (PFS)
- To assess Leukemia-Free Survival (LFS)
- To assess Event-free Survival (EFS)
- To assess Overall Survival (OS)

Expansion (Part 2)

- To evaluate the changes from baseline in fatigue

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

Sabatolimab 400 mg/4mL, Venetoclax 100 mg, Venetoclax 50 mg, Venetoclax 10 mg

In each 28 day-cycle:

- azacitidine was to be administered intravenously or subcutaneously at 75 mg/m2 on Days 1 to 7 (or, at discretion of the investigator on Days 1-5 and Day 8-9), during Safety run-in (Part 1) and Expansion (Part 2).
- venetoclax was to be administered orally at 400 mg daily for 14 consecutive days, during Safety run-in (Part 1) and Expansion (Part 2). No ramp-up of venetoclax was considered necessary in this trial.
- sabatolimab was to be administered intravenously at 400 mg (during Safety run-in Cohort 1) or 800 mg (during Safety run-in Cohort 2 and Expansion) on Day 8 (Q4W).

Statistical Methods

Novartis decided to permanently halt recruitment and not start the Expansion (Part 2) of the study in September 2022. All participants on treatment were followed until discontinuation of treatment and the 150 day safety follow-up which resulted in the global LPLV on 08-May-2023. The study data for this report have been analyzed and reported based on all data up to database lock (DBL) on 12-June-2023.

For this clinical study report (CSR), the analysis sets defined included all participants from the safety run-in part. Participants were analyzed according to the dose regimen they were assigned to (sabatolimab 400 mg or 800 mg Q4W columns) and overall.

The Full Analysis Set (FAS) comprised all participants who received at least one dose of study treatment. If a participant were assigned to a specific cohort without any administration of sabatolimab, but received venetoclax or azacitidine, the participant was included in the analysis.

The Safety Set included all participants who received at least one dose of study treatment.

The Dose Determining Set (DDS**)** included all participants from the FAS enrolled in the Safety run-in part who met the minimum exposure criterion and had sufficient safety evaluations, or experienced a dose limiting toxicity (DLT) during the first two cycles.

The sabatolimab and venetoclax pharmacokinetic analysis sets included all participants from the Safety Set who provided at least one evaluable sabatolimab/venetoclax PK concentration.

The primary objective of the Safety run-in (Part 1) of the study was to determine whether sabatolimab 400 mg and 800 mg are safe (i.e. not meeting overdose criteria) when added in combination with azacitidine and venetoclax.

For the Safety run-in part, the primary endpoint was the incidence of DLTs during the first 2 cycles of treatment for participants in the DDS.

The secondary objectives were to assess the overall response rate (ORR), CR/mCR rate, duration of CR, time to CR/mCR, duration of response, duration of CR/mCR, overall survival (OS), event free survival (EFS), progression free

survival (PFS), leukemia free survival (LFS), RBC/platelets transfusion independence, changes from baseline in fatigue, pharmacokinetic, immunogenicity and safety.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:

1. Signed informed consent must be obtained prior to participation in the study
2. Age ≥ 18 years at the date of signing the informed consent form (ICF)
3. Morphologically confirmed diagnosis of myelodysplastic syndrome (MDS) based on 2016 WHO classification (Arber et al, 2016) by local investigator assessment with one of the following Prognostic Risk Categories, based on the revised International Prognostic Scoring System (IPSS-R) (Greenberg et al 2012):
   - Very high (> 6 points)
   - High (> 4.5-6 points)
4. Not immediately eligible for hematopoietic stem-cell transplantation (HSCT) or intensive chemotherapy at the time of screening due to individual clinical factors such as age, comorbidities and performance status, donor availability (de Witte et al 2017)
5. Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1 or 2

Exclusion Criteria:

1. Prior exposure to TIM-3 directed therapy or any BCL-2 inhibitor (including venetoclax) at any time
2. Prior therapy with immune check point inhibitors (e.g. anti-CTLA4, anti-PD-1, anti-PD-L1, or anti-PD-L2) or cancer vaccines is not allowed if the last dose of the drug was administered within 4 months prior to start of treatment
3. Previous first-line treatment for very high risk or high risk myelodysplastic syndromes (based on IPSS-R,Greenberg et al 2012 and Arber et al, 2016) with any antineoplastic agents, approved or investigational, including for example chemotherapy, lenalidomide and hypomethylating agents (HMAs) such as decitabine or azacitidine
   However, a one single cycle of HMAs treatment only started prior to enrollment is allowed.
4. Live vaccine administered within 30 days prior to start of treatment
5. Current use or use within 14 days prior to start of treatment of systemic steroid therapy (> 10 mg/day prednisone or equivalent) or any immunosuppressive therapy. Topical, inhaled, nasal, ophthalmic steroids are allowed. Replacement therapy, steroids given in the context of a transfusion, are allowed and not considered a form of systemic treatment
6. History of severe hypersensitivity reactions to any ingredient of study drug(s) (azacitidine, venetoclax or sabatolimab) or monoclonal antibodies (mAbs) and/or their excipients
7. Participants with Myelodysplastic syndrome (MDS) based on 2016 WHO classification (Arber et al, 2016) with revised International Prognostic Scoring System (IPSS-R) ≤ 4.5

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Participant Flow Table

Overall Study

	sabatolimab (MBG453) 400 mg + AZA + VEN (Part 1 Cohort 1)	sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)	Total
Arm/Group Description	Part 1 Cohort 1: Safety run-in cohort of a lower dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.	
Started	5	15	20
Did not enter post-treatment follow-up	1	5	6
Entered post-treatment follow-up	4	10	14
Completed	0	0	0
Not Completed	5	15	20
Adverse Event	2	7	9
HSCT Planned	2	3	5
Progressive Disease	0	2	2
Death	0	1	1
Post Study Access to Treatment	0	1	1
Withdrawal by Subject	0	1	1
Physician Decision	1	0	1

Baseline Characteristics

	sabatolimab (MBG453) 400 mg + AZA + VEN (Part 1 Cohort 1)	sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)	Total

Arm/Group Description	Part 1 Cohort 1: Safety run-in cohort of a lower dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.	
Number of Participants [units: participants]	5	15	20
Baseline Analysis Population Description	Full Analysis Set (FAS):		
Age Continuous (units: Years) Analysis Population Type: Participants Mean ± Standard Deviation			
	67.2±11.28	69.3±9.45	68.8±9.67
Sex: Female, Male (units: Participants) Analysis Population Type: Participants Count of Participants (Not Applicable)			
Female	0	4	4
Male	5	11	16
Race/Ethnicity, Customized (units: Participants) Analysis Population Type: Participants Count of Participants (Not Applicable)			
White	4	14	18
Unknown	1	1	2

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Primary Outcome Result(s)

Incidence of dose limiting toxicities (DLTs) - All grades (Safety run-in patients only)

Description	Assessment of tolerability of sabatolimab (MBG453) in combination with venetoclax and azacitidine
Time Frame	From Cycle 1 Day 8 to end of Cycle 2 (Cycle = 28 Days)
Analysis Population Description	Dose determining set (DDS): The DDS included all participants from the FAS enrolled in the Safety run-in part who met the minimum exposure criterion and had sufficient safety evaluations or experienced a dose limiting toxicity (DLT) during the first two cycles.

	sabatolimab (MBG453) 400 mg + AZA + VEN (Part 1 Cohort 1)	**sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)**
Arm/Group Description	Part 1 Cohort 1: Safety run-in cohort of a lower dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.
Number of Participants Analyzed [units: participants]	4	13
Incidence of dose limiting toxicities (DLTs) - All grades (Safety run-in patients only) (units: Participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
Number of participants with at least one event	0 (%)	2 (15.38%)
Blood and lymphatic system disorders (Thrombocytopenia)	0 (%)	1 (7.69%)
Nervous system disorders (Haemorrhage intracranial)	0 (%)	1 (7.69%)

Percentage of participants (receiving 800mg sabatolimab) achieving complete remission (CR) per investigator assessment

Description	This endpoint assessed Complete Remission (CR) Rate of participants from Cohort 2 of Part 1 and Part 2 according to Investigator assessment per modified IWG-MDS - Cheson 2006 criteria. CR is defined as follows: bone marrow blasts <=5%, hemoglobin level ≥ 10 g/dL, platelets count ≥ 100*10^9/L, neutrophils count ≥ 1.0*10^9/L, absence of blasts in peripheral blood.

Time Frame	Throughout study completion, approx. 22.4 months
Analysis Population Description	Full Analysis Set (FAS): The Full Analysis Set (FAS) comprises all participants who received at least one dose of study treatment. If a participant were assigned to a specific cohort without any administration of sabatolimab, but received venetoclax or azacitidine, the participant is included in the analysis.

	sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)
Arm/Group Description	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.
Number of Participants Analyzed [units: participants]	15
Percentage of participants (receiving 800mg sabatolimab) achieving complete remission (CR) per investigator assessment (units: Participants)	**Count of Participants (Not Applicable)**
	1 (6.67%)

Secondary Outcome Result(s)

Percentage of subjects achieving a complete remission (CR) + morphologic complete remission (mCR): Safety run-in (Part 1)

Description	Assessed the durability of complete remission (CR) or morphologic complete remission (mCR) rate (defined as the percentage of participants with best overall response of either CR or mCR).
Time Frame	Throughout study completion, approx. 22.4 months
Analysis Population Description	Full Analysis Set (FAS): The Full Analysis Set (FAS) comprises all participants who received at least one dose of study treatment. If a participant were assigned to a specific cohort without any administration of sabatolimab, but received venetoclax or azacitidine, the participant is included in the analysis.

	sabatolimab (MBG453) 400 mg + AZA + VEN (Part 1 Cohort 1)	sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)
Arm/Group Description	Part 1 Cohort 1: Safety run-in cohort of a lower dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.
Number of Participants Analyzed [units: participants]	5	15
Percentage of subjects achieving a complete remission (CR) + morphologic complete remission (mCR): Safety run-in (Part 1) (units: Participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
	4 (80%)	13 (86.67%)

Overall Response Rate (ORR) of participants who achieved hematologic improvement (HI) or better as best response

Description	The percentage of participants achieving [CR + mCR + partial remission (PR) + hematologic improvement (HI)], per modified IWG-MDS Cheson 2006 criteria
Time Frame	Throughout study completion, approx. 22.4 months
Analysis Population Description	Full Analysis Set (FAS): The Full Analysis Set (FAS) comprises all participants who received at least one dose of study treatment. If a participant were assigned to a specific cohort without any administration of sabatolimab, but received venetoclax or azacitidine, the participant is included in the analysis.

	sabatolimab (MBG453) 400 mg + AZA + VEN (Part 1 Cohort 1)	sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)
Arm/Group Description	Part 1 Cohort 1: Safety run-in cohort of a lower dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.
Number of Participants Analyzed [units: participants]	5	15
Overall Response Rate (ORR) of participants who achieved hematologic improvement (HI) or better as best response (units: Participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**

	4 (80%)	13 (86.67%)

Percentage of participants who are RBC/platelets transfusion independent

Description	Improvement in red blood cells (RBC)/platelets transfusion post-baseline as per International Working Group - Myelodysplastic syndromes (IWG-MDS) by dose level for the safety run-in part (Cohort 1 (400 mg Q4W) and Cohort 2 (800 mg Q4W)) and for participants treated with sabatolimab 800 mg (Q4W) (Cohort 2 of safety run-in and expansion parts).
Time Frame	Throughout study completion, approx. 22.4 months
Analysis Population Description	Full Analysis Set (FAS): The Full Analysis Set (FAS) comprises all participants who received at least one dose of study treatment. If a participant were assigned to a specific cohort without any administration of sabatolimab, but received venetoclax or azacitidine, the participant is included in the analysis.

	sabatolimab (MBG453) 400 mg + AZA + VEN (Part 1 Cohort 1)	**sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)**
Arm/Group Description	Part 1 Cohort 1: Safety run-in cohort of a lower dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.
Number of Participants Analyzed [units: participants]	5	15
Percentage of participants who are RBC/platelets transfusion independent (units: Participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
RBC	2 (40%)	5 (33.33%)
Platelets	2 (40%)	7 (46.67%)

Duration of transfusion independence

Description	Sum of each period of the transfusion independence for participants with at least one period of transfusion independence post-baseline by dose level for the safety run-in part (Cohort 1 (400 mg Q4W) and Cohort 2 (800 mg Q4W)) and for participants treated with sabatolimab 800 mg (Q4W) (Cohort 2 of safety run-in and expansion parts) for both red blood cells and platelets.

Time Frame	Throughout study completion, approx. 22.4 months
Analysis Population Description	Full Analysis Set (FAS): The Full Analysis Set (FAS) comprises all participants who received at least one dose of study treatment. If a participant were assigned to a specific cohort without any administration of sabatolimab, but received venetoclax or azacitidine, the participant is included in the analysis. Analysis is based on participants with at least one period of transfusion independence post-baseline.

	sabatolimab (MBG453) 400 mg + AZA + VEN (Part 1 Cohort 1)	**sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)**
Arm/Group Description	Part 1 Cohort 1: Safety run-in cohort of a lower dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.
Number of Participants Analyzed [units: participants]	5	15
Duration of transfusion independence (units: Weeks)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Packed Red Blood Cells (n = 2, 5)	16.43 ± 0.808	23.11 ± 12.636
Platelets (n = 2, 7)	18.93 ± 2.727	24.02 ± 16.423

Peak Serum Concentration (Cmax) of sabatolimab

Description	Maximal concentration of sabatolimab for participants treated with sabatolimab by dose level for the safety run-in part (Cohort 1 (400 mg Q4W) and Cohort 2 (800 mg Q4W)).
Time Frame	Continuously collected for patients during treatment with sabatolimab up to 150 days after last treatment, approx. 14.2 months
Analysis Population Description	PK analysis set: The sabatolimab and venetoclax pharmacokinetic analysis sets included all participants from the Safety Set who provided at least one evaluable sabatolimab/venetoclax PK concentration. No data is reported as only pre-dose samples were collected

	sabatolimab (MBG453) 400 mg + AZA + VEN (Part 1 Cohort 1)	**sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)**
Arm/Group Description	Part 1 Cohort 1: Safety run-in cohort of a lower dose of sabatolimab in	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in

	combination with fixed dose of venetoclax and azacitidine.	combination with fixed dose of venetoclax and azacitidine.
Number of Participants Analyzed [units: participants]	0	0
Peak Serum Concentration (Cmax) of sabatolimab (units: ug/ml)	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**

Trough Serum Concentration (Cmin) sabatolimab

Description	Concentration of sabatolimab prior to next dosing or after end of treatment by dose level for the safety run-in part (Cohort 1 (400 mg Q4W) and Cohort 2 (800 mg Q4W)).
Time Frame	Continuously collected for patients during treatment with sabatolimab up to 150 days after last treatment, approx. 14.2 months
Analysis Population Description	PK analysis set: The sabatolimab pharmacokinetic analysis set included all participants from the Safety Set who provided at least one evaluable sabatolimab PK concentration.

	sabatolimab (MBG453) 400 mg + AZA + VEN (Part 1 Cohort 1)	**sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)**
Arm/Group Description	Part 1 Cohort 1: Safety run-in cohort of a lower dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.
Number of Participants Analyzed [units: participants]	5	13
Trough Serum Concentration (Cmin) sabatolimab (units: ug/ml)	**Geometric Mean (Geometric Coefficient of Variation)**	**Geometric Mean (Geometric Coefficient of Variation)**
Cycle (C) 1 Day (D) 8 (n = 4, 12)	0.0 (0.0%)	0.0 (0.0%)
C2D8 (n = 4, 10)	23.0 (137.0%)	30.7 (41.7%)
C3D8 (n = 1, 6)	0.0 (0.0%)	34.4 (72.2%)
C6D8 (n = 0, 3)		68.6 (11.5%)
C9D8 (n = 0, 2)		71.2 (33.8%)

C12D (n = 0, 1) 0.0 (0.0%)

Anti-drug Antibody (ADA) prevalence at baseline and ADA incidence on-treatment by dose level

Description	Immunogenicity of sabatolimab prior to sabatolimab exposure and during treatment
Time Frame	Continuously collected for patients during treatment with sabatolimab up to 150 days after last treatment, approx. 14.2 months
Analysis Population Description	Immunogenicity (IG) analysis set: included all participants in the Full Analysis Set with a non-missing baseline IG sample or at least one non-missing post-baseline IG sample. A non-missing IG sample was a sample that was analyzed and not ADA-inconclusive.

	sabatolimab (MBG453) 400 mg + AZA + VEN (Part 1 Cohort 1)	**sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)**
Arm/Group Description	Part 1 Cohort 1: Safety run-in cohort of a lower dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.
Number of Participants Analyzed [units: participants]	4	13
Anti-drug Antibody (ADA) prevalence at baseline and ADA incidence on-treatment by dose level (units: Participants)		
ADA prevalence at baseline	0	2
ADA incidence (i.e., ADA positive) on-treatment	1	2
Treatment-induced ADA-positive	1	1
Treatment-boosted ADA-positive	0	1

Duration of complete remission (CR)

Description	Duration of CR is defined as time from first occurrence of CR to relapse from CR, progression or death due to any cause whichever occurs first for the safety run-in part (Cohort 2 (800 mg Q4W)).
Time Frame	Throughout study completion, approx. 22.4 months

Analysis Population Description	Full Analysis Set (FAS): The Full Analysis Set (FAS) comprises all participants who received at least one dose of study treatment. Analysis is based on participants with CR.

	sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)
Arm/Group Description	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.
Number of Participants Analyzed [units: participants]	1
Duration of complete remission (CR) (units: months)	**Median (95% Confidence Interval)**
	NA (NA to NA)[1]

[1] NA: not enough evens to calculate the median and 95% confidence interval

Time to complete remission(CR)/marrow complete remission (mCR)

Description	Time to CR/mCR is defined as time from start of treatment to first occurrence of CR or mCR as per investigator assessment for the safety run-in part (Cohort 2 (800 mg Q4W)).
Time Frame	Throughout study completion, approx. 22.4 months
Analysis Population Description	Full Analysis Set (FAS): The Full Analysis Set (FAS) comprises all participants who received at least one dose of study treatment.

	sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)
Arm/Group Description	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.
Number of Participants Analyzed [units: participants]	15

Time to complete remission(CR)/marrow complete remission (mCR) (units: months)	**Median (95% Confidence Interval)**
	2.33 (1.61 to 2.83)

Duration of complete response (CR)/marrow complete response (mCR)

Description	Duration of CR/mCR is defined as time from first occurrence of CR/mCR to relapse from CR, progression or death due to any cause whichever occurs first for the safety run-in part (Cohort 2 (800 mg Q4W)).
Time Frame	Throughout study completion, approx. 22.4 months
Analysis Population Description	Full Analysis Set (FAS): The Full Analysis Set (FAS) comprises all participants who received at least one dose of study treatment. Analysis is based on participants with CR or mCR.

	sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)
Arm/Group Description	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.
Number of Participants Analyzed [units: participants]	13
Duration of complete response (CR)/marrow complete response (mCR) (units: months)	**Median (95% Confidence Interval)**
	5.60 (4.14 to NA)[1]

[1] NA: with the small sample size and limited follow-up, the survival curve just barely reached the median, so a finite CI upper limit could not be reached.

Duration of response for participants who achieved hematologic improvement (HI) or better

Description	The duration of response was derived for participants treated with sabatolimab at the higher dose who achieved HI or better as per investigator assessment and is defined from the first occurrence of complete response (CR), marrow complete response (mCR), partial response (PR) or hematologic improvement (HI) until relapse, progression or death due to any reason for the safety run-in part (Cohort 2 (800 mg Q4W)).
Time Frame	Throughout study completion, approx. 22.4 months

Analysis Population Description	Full Analysis Set (FAS): The Full Analysis Set (FAS) comprises all participants who received at least one dose of study treatment. Analysis is based on participants with CR, mCR, PR or HI.

	sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)
Arm/Group Description	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.
Number of Participants Analyzed [units: participants]	13
Duration of response for participants who achieved hematologic improvement (HI) or better (units: months)	**Median (95% Confidence Interval)**
	5.60 (4.14 to NA)[1]

[1] NA: with the small sample size and limited follow-up, the survival curve just barely reached the median, so a finite CI upper limit could not be reached.

Progression-Free Survival (PFS)

Description	Time from start of treatment to disease progression (including transformation to acute leukemia per WHO 2016 classification), relapse from CR or death due to any cause, whichever occurs first for the safety run-in part (Cohort 2 (800 mg Q4W)).
Time Frame	Throughout study completion, approx. 22.4 months
Analysis Population Description	Full Analysis Set (FAS): The Full Analysis Set (FAS) comprises all participants who received at least one dose of study treatment.

	sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)
Arm/Group Description	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.
Number of Participants Analyzed [units: participants]	15

Progression-Free Survival (PFS) (units: months)	**Median** **(95% Confidence Interval)**
	6.77 (3.71 to NA)[1]

[1] NA: with the small sample size and limited follow-up, the survival curve just barely reached the median, so a finite CI upper limit could not be reached.

Leukemia-Free Survival (LFS)

Description	Time from start of treatment to transformation to acute leukemias per investigator assessment [as defined as ≥ 20% blasts in bone marrow/ peripheral blood (per WHO 2016 classification) or diagnosis of extramedullary acute leukemia or death due to any cause, whichever occurs first for the safety run-in part (Cohort 2 (800 mg Q4W)).
Time Frame	Throughout study completion, approx. 22.4 months
Analysis Population Description	Full Analysis Set (FAS): The Full Analysis Set (FAS) comprises all participants who received at least one dose of study treatment.

	sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)
Arm/Group Description	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.
Number of Participants Analyzed [units: participants]	15
Leukemia-Free Survival (LFS) (units: months)	**Median** **(95% Confidence Interval)**
	7.59 (4.24 to NA)[1]

[1] NA: with the small sample size and limited follow-up, the survival curve just barely reached the median, so a finite CI upper limit could not be reached.

Event-Free Survival (EFS)

Description	Time from start of treatment to lack of reaching CR within the first 6 cycles, relapse from CR or death due to any cause, whichever occurs first for the safety run-in part (Cohort 2 (800 mg Q4W)).
Time Frame	Throughout study completion, approx. 22.4 months

Analysis Population Description	Full Analysis Set (FAS): The Full Analysis Set (FAS) comprises all participants who received at least one dose of study treatment.

	sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)
Arm/Group Description	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.
Number of Participants Analyzed [units: participants]	15
Event-Free Survival (EFS) (units: months)	**Median (95% Confidence Interval)**
	0.03 (NA to NA)[1]

[1] NA: lower and upper limit of 95 Confidence Interval could not be reached because most participants had an EFS event on Day 1 due to treatment failure

Overall Survival (OS)

Description	Time from start of treatment to death due to any cause for the safety run-in part (Cohort 2 (800 mg Q4W)).
Time Frame	Date of start of treatment to date of death due to any reason, for up to approx. 22.4 months
Analysis Population Description	Full Analysis Set (FAS): The Full Analysis Set (FAS) comprises all participants who received at least one dose of study treatment.

	sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)
Arm/Group Description	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.
Number of Participants Analyzed [units: participants]	15

Overall Survival (OS) (units: months)	**Median** **(95% Confidence Interval)**
	NA (677 to NA)[1]

[1] NA: median and upper limit of 95 Confidence Interval could not be reached because of small sample size and limited survival follow up due to study termination of study

Changes in fatigue (Part 2 - Expansion)

Description	Changes in fatigue as measured by the Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue for participants treated with sabatolimab at the higher dose of the expansion part only. Measurements would have been taken via scores from 0 (not at all) to 4 (very much). The higher the score, the better the Quality of Life.
Time Frame	Throughout study completion, approx. 22.4 months
Analysis Population Description	As expansion phase was not opened, there is no data as nothing was analyzed.

	sabatolimab (MBG453) 800 mg + AZA + VEN (Part 2)
Arm/Group Description	Part 2 Expansion: higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.
Number of Participants Analyzed [units: participants]	0
Changes in fatigue (Part 2 - Expansion) (units:)	**()**

Other Pre-Specified Outcome Result(s)

No data identified.

Post-Hoc Outcome Result(s)

All Collected Deaths

Description	On-treatment deaths were collected from start of study treatment (FPFT) up to 30 days after study drug discontinuation, for a maximum duration of approx. 13 months. Post-treatment survival follow-up deaths were collected from Day 31 after last dose of study treatment to end of study up to approx. 18.4 months All deaths refer to the sum of on-treatment and post-treatment survival follow-up deaths, approx. 22.4 months.
Time Frame	On-treatment deaths: up to approx. 13 months, post-treatment deaths: up to approx 18.4 months
Analysis Population Description	All enrolled patients

	sabatolimab (MBG453) 400 mg + AZA + VEN (Part 1 Cohort 1)	**sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2)**
Arm/Group Description	Part 1 Cohort 1: Safety run-in cohort of a lower dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.	Part 1 Cohort 2: Safety run-in cohort of a higher dose of sabatolimab in combination with fixed dose of venetoclax and azacitidine.
Number of Participants Analyzed [units: participants]	5	15
All Collected Deaths (units: Participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
All deaths	1 (20%)	6 (40%)
On-treatment deaths	0 (%)	1 (6.67%)
Post-treatment deaths	1 (20%)	5 (35.71%)

Safety Results

Time Frame	Adverse events were collected from first dose of study treatment to 150 days after last dose of study medication (on-treatment), for sabatolimab and 30 days for azactidine & venetoclax up to approx. 13 months. Deaths were collected in the post treatment survival follow up from 31 days after last dose of study medication until the end of the study, up to approx. 18.4 months. These are not considered AEs
Additional Description	Any sign or symptom that occurs during the conduct of the trial and safety follow-up. Deaths in the post treatment survival follow-up are not considered Adverse Events. The total number at risk in the post treatment survival includes patients that entered the post treatment survival follow-up period.
Source Vocabulary for Table Default	MedDRA (26.0)
Collection Approach for Table Default	Systematic Assessment

All-Cause Mortality

	sabatolimab (MBG453) 400 mg + AZA + VEN (Part 1 Cohort 1) - On-treatment N = 5	**sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2) - On-treatment N = 15**	**sabatolimab (MBG453) 400 mg + AZA + VEN (Part 1 Cohort 1) - Post-treatment survival follow-up N = 5**	**sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2) - Post-treatment survival follow-up N = 14**
Arm/Group Description	Adverse Events (AEs) during on-treatment period (up to 30 days post-treatment)	Adverse Events (AEs) during on-treatment period (up to 30 days post-treatment)	Deaths collected in the post- treatment survival follow-up phase (starting from day 31 post-treatment). No AEs were collected during this period	Deaths collected in the post- treatment survival follow-up phase (starting from day 31 post-treatment). No AEs were collected during this period
Total Number Affected	0	1	1	5
Total Number At Risk	5	15	5	14

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Serious Adverse Events

Time Frame	Adverse events were collected from first dose of study treatment to 150 days after last dose of study medication (on-treatment), for sabatolimab and 30 days for azactidine & venetoclax up to approx. 13 months. Deaths were collected in the post treatment survival follow up from 31 days after last dose of study medication until the end of the study, up to approx. 18.4 months. These are not considered AEs
Additional Description	Any sign or symptom that occurs during the conduct of the trial and safety follow-up. Deaths in the post treatment survival follow-up are not considered Adverse Events. The total number at risk in the post treatment survival includes patients that entered the post treatment survival follow-up period.
Source Vocabulary for Table Default	MedDRA (26.0)
Collection Approach for Table Default	Systematic Assessment

	sabatolimab (MBG453) 400 mg + AZA + VEN (Part 1 Cohort 1) - On-treatment N = 5	**sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2) - On-treatment N = 15**	**sabatolimab (MBG453) 400 mg + AZA + VEN (Part 1 Cohort 1) - Post-treatment survival follow-up N = 0**	**sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2) - Post-treatment survival follow-up N = 0**
Arm/Group Description	Adverse Events (AEs) during on-treatment period (up to 30 days post-treatment)	Adverse Events (AEs) during on-treatment period (up to 30 days post-treatment)	Deaths collected in the post- treatment survival follow-up phase (starting from day 31 post-treatment). No AEs were collected during this period	Deaths collected in the post- treatment survival follow-up phase (starting from day 31 post-treatment). No AEs were collected during this period
Total # Affected by any Serious Adverse Event	3	14	0	0

Total # at Risk by any Serious Adverse Event	5	15	0	0
Blood and lymphatic system disorders				
Anaemia	0 (0.00%)	2 (13.33%)		
Febrile bone marrow aplasia	1 (20.00%)	0 (0.00%)		
Febrile neutropenia	2 (40.00%)	5 (33.33%)		
Neutropenia	1 (20.00%)	0 (0.00%)		
Pancytopenia	1 (20.00%)	0 (0.00%)		
Thrombocytopenia	1 (20.00%)	0 (0.00%)		
Gastrointestinal disorders				
Gastrointestinal haemorrhage	0 (0.00%)	1 (6.67%)		
Large intestine perforation	0 (0.00%)	1 (6.67%)		
General disorders and administration site conditions				
Pyrexia	0 (0.00%)	1 (6.67%)		
Immune system disorders				
Autoinflammatory disease	0 (0.00%)	1 (6.67%)		
Infections and infestations				
Bacterial sepsis	1 (20.00%)	0 (0.00%)		
COVID-19	0 (0.00%)	1 (6.67%)		
Escherichia bacteraemia	0 (0.00%)	1 (6.67%)		
Gastroenteritis viral	0 (0.00%)	1 (6.67%)		

Peritonitis	0 (0.00%)	1 (6.67%)
Sepsis	1 (20.00%)	1 (6.67%)
Septic shock	0 (0.00%)	1 (6.67%)
Injury, poisoning and procedural complications		
Limb injury	0 (0.00%)	1 (6.67%)
Wound haemorrhage	0 (0.00%)	1 (6.67%)
Investigations		
Medical observation	0 (0.00%)	1 (6.67%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Lung adenocarcinoma	1 (20.00%)	0 (0.00%)
Paraneoplastic syndrome	0 (0.00%)	1 (6.67%)
Nervous system disorders		
Haemorrhage intracranial	0 (0.00%)	1 (6.67%)

Other (Not Including Serious) Adverse Events

Time Frame	Adverse events were collected from first dose of study treatment to 150 days after last dose of study medication (on-treatment), for sabatolimab and 30 days for azactidine & venetoclax up to approx. 13 months. Deaths were collected in the post treatment survival follow up from 31 days after last dose of study medication until the end of the study, up to approx. 18.4 months. These are not considered AEs

Additional Description	Any sign or symptom that occurs during the conduct of the trial and safety follow-up. Deaths in the post treatment survival follow-up are not considered Adverse Events. The total number at risk in the post treatment survival includes patients that entered the post treatment survival follow-up period.
Source Vocabulary for Table Default	MedDRA (26.0)
Collection Approach for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	5%

	sabatolimab (MBG453) 400 mg + AZA + VEN (Part 1 Cohort 1) - On-treatment N = 5	**sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2) - On-treatment N = 15**	**sabatolimab (MBG453) 400 mg + AZA + VEN (Part 1 Cohort 1) - Post-treatment survival follow-up N = 0**	**sabatolimab (MBG453) 800 mg + AZA + VEN (Part 1 Cohort 2) - Post-treatment survival follow-up N = 0**
Arm/Group Description	Adverse Events (AEs) during on-treatment period (up to 30 days post-treatment)	Adverse Events (AEs) during on-treatment period (up to 30 days post-treatment)	Deaths collected in the post- treatment survival follow-up phase (starting from day 31 post-treatment). No AEs were collected during this period	Deaths collected in the post- treatment survival follow-up phase (starting from day 31 post-treatment). No AEs were collected during this period
Total # Affected by any Other Adverse Event	5	15	0	0
Total # at Risk by any Other Adverse Event	5	15	0	0
Blood and lymphatic system disorders				
Anaemia	1 (20.00%)	7 (46.67%)		

Bone marrow failure	1 (20.00%)	0 (0.00%)
Febrile neutropenia	0 (0.00%)	2 (13.33%)
Haemolysis	1 (20.00%)	0 (0.00%)
Leukopenia	1 (20.00%)	0 (0.00%)
Neutropenia	3 (60.00%)	8 (53.33%)
Pancytopenia	0 (0.00%)	2 (13.33%)
Thrombocytopenia	3 (60.00%)	7 (46.67%)
Thrombocytosis	0 (0.00%)	1 (6.67%)
Cardiac disorders		
Sinus bradycardia	0 (0.00%)	1 (6.67%)
Gastrointestinal disorders		
Abdominal pain	0 (0.00%)	2 (13.33%)
Abdominal pain upper	1 (20.00%)	0 (0.00%)
Constipation	2 (40.00%)	4 (26.67%)
Diarrhoea	2 (40.00%)	2 (13.33%)
Eructation	0 (0.00%)	1 (6.67%)
Flatulence	1 (20.00%)	0 (0.00%)
Haemorrhoidal haemorrhage	1 (20.00%)	0 (0.00%)
Haemorrhoids	0 (0.00%)	1 (6.67%)
Lower gastrointestinal haemorrhage	0 (0.00%)	1 (6.67%)
Nausea	1 (20.00%)	6 (40.00%)
Odynophagia	0 (0.00%)	1 (6.67%)

Stomatitis	1 (20.00%)	3 (20.00%)
Toothache	1 (20.00%)	0 (0.00%)
Vomiting	1 (20.00%)	3 (20.00%)
General disorders and administration site conditions		
Asthenia	1 (20.00%)	3 (20.00%)
Catheter site inflammation	0 (0.00%)	1 (6.67%)
Chills	0 (0.00%)	1 (6.67%)
Device related thrombosis	0 (0.00%)	1 (6.67%)
Fatigue	1 (20.00%)	2 (13.33%)
Hyperthermia	0 (0.00%)	1 (6.67%)
Infusion site haematoma	0 (0.00%)	1 (6.67%)
Injection site erythema	0 (0.00%)	1 (6.67%)
Injection site pain	0 (0.00%)	1 (6.67%)
Injection site reaction	1 (20.00%)	0 (0.00%)
Oedema peripheral	0 (0.00%)	2 (13.33%)
Peripheral swelling	0 (0.00%)	1 (6.67%)
Pyrexia	0 (0.00%)	2 (13.33%)
Hepatobiliary disorders		
Cholestasis	1 (20.00%)	1 (6.67%)
Hepatic cytolysis	0 (0.00%)	1 (6.67%)
Hepatotoxicity	0 (0.00%)	1 (6.67%)
Hyperbilirubinaemia	1 (20.00%)	1 (6.67%)

Hypertransaminasaemia	0 (0.00%)	1 (6.67%)
Jaundice	0 (0.00%)	1 (6.67%)
Infections and infestations		
Cellulitis	0 (0.00%)	1 (6.67%)
Clostridium bacteraemia	0 (0.00%)	1 (6.67%)
COVID-19	0 (0.00%)	1 (6.67%)
Escherichia bacteraemia	0 (0.00%)	1 (6.67%)
Oral herpes	0 (0.00%)	1 (6.67%)
Sepsis	0 (0.00%)	1 (6.67%)
Tooth abscess	1 (20.00%)	0 (0.00%)
Vascular device infection	0 (0.00%)	1 (6.67%)
Investigations		
Blood bilirubin increased	0 (0.00%)	1 (6.67%)
Blood folate decreased	0 (0.00%)	1 (6.67%)
Blood lactate dehydrogenase increased	0 (0.00%)	1 (6.67%)
Blood urea increased	0 (0.00%)	1 (6.67%)
C-reactive protein increased	0 (0.00%)	2 (13.33%)
Gamma-glutamyltransferase increased	0 (0.00%)	1 (6.67%)
Neutrophil count decreased	1 (20.00%)	2 (13.33%)
Platelet count decreased	0 (0.00%)	3 (20.00%)
Serum ferritin decreased	0 (0.00%)	1 (6.67%)
Troponin T increased	0 (0.00%)	1 (6.67%)

Weight decreased	0 (0.00%)	1 (6.67%)
White blood cell count decreased	0 (0.00%)	1 (6.67%)
Metabolism and nutrition disorders		
Cell death	1 (20.00%)	0 (0.00%)
Decreased appetite	0 (0.00%)	1 (6.67%)
Gout	1 (20.00%)	0 (0.00%)
Hyperkalaemia	0 (0.00%)	1 (6.67%)
Hypernatraemia	0 (0.00%)	1 (6.67%)
Hyperuricaemia	0 (0.00%)	1 (6.67%)
Hypokalaemia	1 (20.00%)	2 (13.33%)
Hypomagnesaemia	0 (0.00%)	1 (6.67%)
Hypophosphataemia	0 (0.00%)	1 (6.67%)
Malnutrition	0 (0.00%)	1 (6.67%)
Tumour lysis syndrome	0 (0.00%)	1 (6.67%)
Vitamin K deficiency	0 (0.00%)	1 (6.67%)
Musculoskeletal and connective tissue disorders		
Arthralgia	0 (0.00%)	1 (6.67%)
Myalgia	0 (0.00%)	1 (6.67%)
Pain in extremity	1 (20.00%)	0 (0.00%)
Tendonitis	0 (0.00%)	1 (6.67%)
Nervous system disorders		
Dizziness	0 (0.00%)	1 (6.67%)

Haemorrhage intracranial	0 (0.00%)	1 (6.67%)
Headache	0 (0.00%)	1 (6.67%)
Psychiatric disorders		
Anxiety	0 (0.00%)	2 (13.33%)
Confusional state	0 (0.00%)	1 (6.67%)
Renal and urinary disorders		
Haematuria	0 (0.00%)	1 (6.67%)
Renal impairment	0 (0.00%)	1 (6.67%)
Reproductive system and breast disorders		
Cervical polyp	0 (0.00%)	1 (6.67%)
Heavy menstrual bleeding	0 (0.00%)	1 (6.67%)
Uterine haemorrhage	0 (0.00%)	1 (6.67%)
Respiratory, thoracic and mediastinal disorders		
Cough	1 (20.00%)	0 (0.00%)
Epistaxis	0 (0.00%)	1 (6.67%)
Pleural effusion	1 (20.00%)	0 (0.00%)
Skin and subcutaneous tissue disorders		
Dermatitis allergic	0 (0.00%)	1 (6.67%)
Erythema	0 (0.00%)	1 (6.67%)
Pruritus	1 (20.00%)	2 (13.33%)
Purpura	0 (0.00%)	1 (6.67%)

Rash maculo-papular	0 (0.00%)	1 (6.67%)
Rash pruritic	0 (0.00%)	1 (6.67%)
Vascular disorders		
Haematoma	0 (0.00%)	1 (6.67%)
Hypertension	0 (0.00%)	1 (6.67%)
Hypotension	0 (0.00%)	1 (6.67%)
Thrombosis	0 (0.00%)	1 (6.67%)

Other Relevant Findings

Not Applicable

Conclusion:

Due to the limited recruitment, limited efficacy data were collected in this study, and no conclusions can be made regarding the efficacy of the triplet combination sabatolimab + azacitidine + venetoclax in high risk MDS patients.

No major safety issues were identified during the Safety run-in (Part 1) and the combination of sabatolimab with azacitidine 75 mg/m2 and venetoclax 400 mg QD was considered safe and well tolerated at the two sabatolimab dose levels tested (400 mg Q4W and 800 mg Q4W). Most commonly reported adverse events were consistent with the known safety profile reported in MDS patients treated with venetoclax and azacitidine.

Date of Clinical Trial Report

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