A RANDOMIZED, 2-ARM, PHASE 3 STUDY OF ELRANATAMAB (PF-06863135) VERSUS LENALIDOMIDE IN PATIENTS WITH NEWLY DIAGNOSED MULTIPLE MYELOMA AFTER UNDERGOING AUTOLOGOUS STEM-CELL TRANSPLANTATION

Published: 01-03-2022
Last updated: 25-09-2024

This study has been transitioned to CTIS with ID 2023-508897-27-00 check the CTIS register for the current data. Primary:• To compare the efficacy of elranatamab vs lenalidomide Secondary:- To compare the efficacy of elranatamab vs lenalidomide- To...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	White blood cell disorders
Study type	Interventional

Summary

ID

NL-OMON56205

Source
ToetsingOnline

Brief title
MAGNETISMM-7

Condition

- White blood cell disorders

Synonym
bone marrow cancer cells, Malignant plasmacells

Research involving
Human

Sponsors and support

Primary sponsor: Pfizer
Source(s) of monetary or material Support: industry

Intervention

Keyword: Elranatamab, MULTIPLE MYELOMA, Phase 3

Outcome measures

Primary outcome

• PFS by BICR per IMWG

Secondary outcome

• OS

• MRD negativity rate at 12 months after randomization per IMWG as assessed via

NGS PFS by investigator per IMWG

• Sustained MRD negativity rate at 24 months after randomization as

assessed via NGS

• PFS by investigator per IMWG

• Overall MRD negativity rate per IMWG

• Duration of MRD negativity per IMWG

• Sustained MRD negativity per IMWG

• CRR by BICR and investigator per IMWG

• DOCR by BICR and investigator per IMWG

• PFS2 by Investigator per IMWG

• AEs and laboratory abnormalities as graded by NCI CTCAE v5.0.

• Severity of CRS and ICANS assessed according to ASTCT criteria

• Pre- and postdose concentrations of elranatamab

• ADAs and Nabs against elranatamab

• EORTC QLQ-C30 and MY20

Study description

Background summary

Multiple myeloma is a blood cancer and is characterized by typical manifestations of organ damage such as bone lesions, increased calcium level in blood, low number of red blood cells and kidney damage. Despite recent advances in treatment, multiple myeloma remains an incurable disease and almost all patients, even those who initially respond to treatment, are expected to relapse.

Elranatamab is a type of antibody drug. Antibodies are a part of the immune system. Elranatamab binds to T-cells (a type of immune system cell) and myeloma cells; this causes the T-cells to kill the myeloma cells. Elranatamab is considered investigational drug because it is not approved for use in the Netherlands.

Lenalidomide is a drug that changes the immune response, and targets and kills myeloma cells. It helps your immune system recognize and destroy myeloma cells and prevents new myeloma cell growth by starving them of blood. Lenalidomide was selected as the comparator drug in this study as it is considered the standard of care therapy and the only approved maintenance therapy following an ASCT.

Study objective

This study has been transitioned to CTIS with ID 2023-508897-27-00 check the CTIS register for the current data.

Primary:
• To compare the efficacy of elranatamab vs lenalidomide

Secondary:
- To compare the efficacy of elranatamab vs lenalidomide
- To determine the safety and tolerability of elranatamab
- To evaluate the PK of elranatamab
- To evaluate the immunogenicity of elranatamab
- To evaluate the impact of study intervention on participant health-related

quality of life (HRQoL)

Tertiary/Exploratory:
- To explore the relationship between elranatamab and the biology of the participant*s MM
- To explore correlations between elranatamab exposure and efficacy, safety and biomarker endpoints, if data allow
- To assess the impact of study intervention on patient-reported symptoms and functioning
- To collect healthcare resource use data

Study design

Study C1071007 is a Phase 3, open-label, randomized, 2-arm study of elranatamab monotherapy vs lenalidomide in participants with newly diagnosed multiple myeloma after undergoing ASCT.

Intervention

Arm A: The people in this group will get elranatamab
Arm B: The people in this group will get lenalidomide
Arm C: The people in this group will get elranatamab

Study burden and risks

The subjects participation may help future patients by increasing our understanding of elranatamab in treating multiple myeloma. It is possible that their condition or health may improve, worsen, or stay the same.

The subject may experience the side effects or adverse effects of the study drug, as described in Section 6 of the main ICD. There may be some discomfort from the measurements during the study. Taking part in the study will cost the subject extra time, and he/she will need to be hospitalized.

Based on data from the ongoing Phase 1 study, elranatamab monotherapy has demonstrated the potential to convert heavily pretreated patients with relapsed/refractory multiple myeloma to MRD-negative status. Therefore, and consequently it is expected to provide clinical benefit including the potential for a prolonged progression-free disease to participants with newly diagnosed multiple myeloma with MRD-positive status after undergoing ASCT with an acceptable and manageable safety profile. All participants will benefit from close monitoring that go beyond the SOC in the maintenance setting.

Taking into account the measures taken to minimize risk to study participants, the potential risks identified with elranatamab are justified by the anticipated benefits that may be afforded to participants with newly diagnosed

multiple myeloma who are MRD-positive after undergoing ASCT.

Contacts

Public
Pfizer

Rivium Westlaan 142
Capelle a/d IJssel 2909LD
NL
Scientific
Pfizer

Rivium Westlaan 142
Capelle a/d IJssel 2909LD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Diagnosis of MM as defined according to IMWG criteria (Rajkumar, 2014) - with measurable disease at diagnosis as defined by serum M protein >=0.5 g/dL (5 g/L), by urine M protein >=200 mg/24 hours, or by serum FLC assay with involved FLC level >=10 mg/dL, provided serum FLC
ratio is abnormal.

History of induction therapy and autologous stem cell transplant. Randomization must occur within 120 days from the stem cell transplant. For participants who receive consolidation therapy after

ASCT, randomization must occur within 60 days of consolidation and within 7 months from ASCT. Screening tests should be performed after the last dose of consolidation.
- Partial Response or better according to IMWG criteria at the time of randomization
- Identification of the dominant malignant (index) clone as assessed by central laboratory NGS test (Adaptive Biotechnologies clonoSEQ® assay or as described in Appendix 10.9.6).
- Must have an archival bone marrow aspirate sample(s) that identified the dominant malignant (index) clone that is used to track MRD status. This sample should preferably be collected before induction treatment (eg, at diagnosis) or before transplant.
- A bone marrow aspirate sample collected at screening is required to determine MRD status
-ECOG performance status <= 1
- Resolved acute effects of any prior therapy to baseline severity or CTCAE Grade <= 1
- Not pregnant and willing to use contraception

Exclusion criteria

- Plasma cell leukemia
- Amyloidosis, Waldenström's macroglobulinemia, or POEMS syndrome
- Known active CNS involvement or clinical signs of myelomatous meningeal involvement.
- Previous MM maintenance treatment
- Prior treatment with BCMA targeted therapy
- Any other active malignancy within 3 years prior to enrolment, except for adequately treated basal cell or squamous cell skin cancer, or carcinoma in situ or Stage 0/1 with minimal risk of recurrence per the investigator.
- Active, uncontrolled bacterial, fungal, or viral infection, including (but not limited to) HBV, HCV, and known HIV or AIDS-related illness. Active Infection must be resolved at least 21 days prior to enrollment. Patients treated with systemic anti-infectious agents within 28 days prior to enrollment are not eligible. Prophylactic use of systemic agents is permitted.
- Previous administration with an investigational drug or vaccine within 30 days (or as determined by the local requirement) or 5 half lives preceding the first dose of study intervention used in this study (whichever is longer)

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-01-2023
Enrollment:	20
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	Elranatamab
Generic name:	Elranatamab
Product type:	Medicine
Brand name:	Revlimid
Generic name:	Lenalidomide
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	01-03-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	25-04-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	15-06-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-09-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-12-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-12-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-03-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	22-05-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-06-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

	(Assen)
Approved WMO Date:	07-08-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-10-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-10-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EU-CTR	CTIS2023-508897-27-00
EudraCT	EUCTR2021-006052-14-NL
ClinicalTrials.gov	NCT05317416
CCMO	NL80153.056.22