Phase 1b/2, Open Label Study to Evaluate Safety and Tolerability of Epcoritamab in Combination with Anti-Neoplastic Agents in Subjects with Non-Hodgkin Lymphoma

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This study has been transitioned to CTIS with ID 2023-505347-38-00 check the CTIS register for the current data. The primary objectives of the study are to characterize the safety and toxicity profiles of epcoritamab when co-administered with anti-...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lymphomas non-Hodgkin's B-cell
Study type	Interventional

Summary

ID

NL-OMON53475

Source
ToetsingOnline

Brief title
M22-132

Condition

- Lymphomas non-Hodgkin's B-cell

Synonym
lymphatic disease, Non-Hodgkin Lymphoma

Research involving
Human

Sponsors and support

Primary sponsor: AbbVie B.V.
Source(s) of monetary or material Support: AbbVie

Intervention

Keyword: B-cell Non-Hodgkin Lymphoma, Epcoritamab, Phase 1b/2

Outcome measures

Primary outcome

The primary endpoint is dose limiting toxicities (DLTs) of epcoritamab in combination with anti-neoplastic agents.

Secondary outcome

• Overall Response Rate (ORR) by Lugano 2014 criteria (Appendix E) as assessed by investigator for epcoritamab in combination with other anti-neoplastic agents.

• Anti-lymphoma activity of epcoritamab in combination with other anti-neoplastic agents:

-Duration of response (DOR) determined per Lugano 2014 criteria as assessed by investigator

-Progression free survival (PFS) determined per Lugano 2014 criteria as assessed by investigator

-Complete Response (CR) rate determined per Lugano 2014 criteria as assessed by investigator

-Time to response (TTR) determined per Lugano 2014 criteria as assessed by investigator

-Time to next anti-lymphoma therapy (TTNT)

-Rate of Minimal Residual Disease (MRD) negativity

-Overall survival (OS)

Study description

Background summary

B-cell Lymphoma is an aggressive and rare cancer of a type of immune cell (a white blood cell responsible for fighting infections). The purpose of this study is to assess the safety and tolerability of epcoritamab in combination with anti-neoplastic agents in adult participants with Non-Hodgkin lymphoma (NHL). Adverse events and change in disease activity will be assessed.

Study objective

This study has been transitioned to CTIS with ID 2023-505347-38-00 check the CTIS register for the current data.

The primary objectives of the study are to characterize the safety and toxicity profiles of epcoritamab when co-administered with anti-neoplastic agents in subjects with B-cell NHL and to determine the recommended dose for further investigation of epcoritamab when co- administered with anti-neoplastic agents in subjects with B-cell NHL.

Study design

Open-Label; Dose-escalation and Dose-expansion Study

Intervention

In both the dose escalation and dose expansion arms participants will receive subcutaneous (SC) epcoritamab in 28-day or 21 day cycles dependent on the arm in combination with the anti-neoplastic agents described below:
1: Oral lenalidomide in participants with relapsed/refractory(R/R) diffuse large B-cell lymphoma (DLBCL);
2: Oral ibrutinib and oral lenalidomide in participants with with R/R DLBCL;
3: Intravenous (IV) polatuzumab vedotin, IVrituximab, IV cyclophosphamide, IV doxorubicin hydrochloride (HCl), and oral prednisone (pola-R-CHP) inparticipants with newly diagnosed treatment-naïve DLBCL;
4: Oral CC-99282 in participants with R/R DLBCL;
5: OralCC-99282 in participants with R/R follicular lymphoma (FL);
6A: Oral ibrutinib in participants with R/R mantle cell lymphoma (MCL);
6B: Oral ibrutinib, and oral venetoclax in participants with R/R MCL;

7: Oral ibrutinib,and oral venetoclax in participants with newly diagnosed treatment-naïve MCL.

Study burden and risks

There may be higher treatment burden for participants in this trial compared to their standard of care. Participants will attend regular visits during the study at an approved institution (hospital or clinic). The effect of the treatment will be frequently checked by medical assessments, blood tests, questionnaires and side effects.

Contacts

Public
AbbVie B.V.

Knollstrasse 50
Ludwigshafen 67061
DE
Scientific
AbbVie B.V.

Knollstrasse 50
Ludwigshafen 67061
DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Adult male or female, at least 18 years old 2. Diagnosis of DLBCL with histologically confirmed CD20+ disease, inclusive of the following according to WHO 2016 classification and documented in pathology report: • DLBCL, not otherwise specified (NOS) • High-grade B cell lymphoma with MYC and BCL-2 and/or BCL-6 translocations per WHO 2016 (*double-hit* or *triple-hit*) Note: High-grade B-cell lymphomas NOS or other double-/triple-hit lymphomas (with histologies not consistent with DLBCL) are not eligible • Follicular lymphoma Grade 3B 3. Subject must have Eastern Cooperative Oncology Group (ECOG) performance status 0 - 2 4. Subject must have 1 or more measurable disease sites: • A positron emission tomography/computed tomography (PET/CT) scan demonstrating PET-positive lesion(s) AND • At least 1 measurable nodal lesion (long axis >= 1.5cm and short axis > 1.0 cm) or >= 1 measurable extra-nodal lesion (long axis >= 1.0 cm) on CT scan or MRI

Exclusion criteria

1.Diagnosis of High-grade B-cell lymphomas NOS or other double-/triple-hit lymphomas (with histologies not consistent with DLBCL)
2. Subjects who have had prior treatment with epcoritamab or any other bispecific antibody targeting CD3 and CD20

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-11-2022
Enrollment:	10

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Epcoritamab
Generic name:	Epcoritamab
Product type:	Medicine
Brand name:	Ibrutinib
Generic name:	Ibrutinib
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Lenalidomide
Generic name:	Lenalidomide
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Polatuzumab vedotin
Generic name:	Polatuzumab vedotin
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Prednisone
Generic name:	Prednisone
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	13-04-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-07-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	06-08-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-09-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-06-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-11-2023
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	CTIS2023-505347-38-00
EudraCT	EUCTR2021-005725-24-NL

Register	ID
ClinicalTrials.gov	NCT05283720
CCMO	NL80499.056.22