P446

EpcoReal: A Prospective Observational Trial-in-Progress of Epcoritamab in Patients With Relapsed/Refractory Diffuse Large B-Cell Lymphoma and Follicular Lymphoma

EpcoReal: eine laufende prospektive Beobachtungsstudie von Epcoritamab bei Patienten mit rezidiviertem/refraktärem diffusem großzelligem B-Zell-Lymphom und follikulärem Lymphom

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OBJECTIVE

To evaluate real-world outcomes in patients with relapsed/refractory (diffuse) large B-cell lymphoma and follicular lymphoma treated with epcoritamab after ≥ 2 prior lines of therapy

STUDY OVERVIEW

Prospective, observational trial

Treatment: Epcoritamab for up to 36 months

Primary Endpoint: Overall response rate

~ 700 patients planned for enrollment:
~ 400 R/R (D)LBCL
~ 300 R/R FL

International:
~ 80 sites in
~ 12–20 countries

NCT06830759

For additional information or to download an electronic version of this presentation, scan the QR code below.

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References

1. Tepkinly [summary of product characteristics]. Ludwigshafen, Germany: AbbVie Deutschland GmbH & Co. KG; October 2024.
2. Thieblemont C, et al. *J Clin Oncol.* 2023;41(12):2238-2247.

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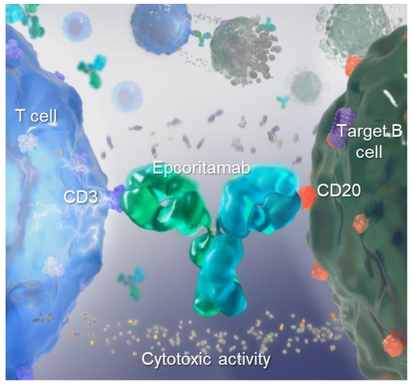
BACKGROUND

- Epcoritamab is a subcutaneously administered CD3xCD20 bispecific T-cell engager approved for the treatment of relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL) after ≥ 2 lines of therapy[1] (**Figure 1**)
- In the phase 1/2 EPCORE NHL-1 trial (NCT03625037), epcoritamab monotherapy resulted in deep and durable responses and a manageable safety profile in patients with R/R B-cell non-Hodgkin lymphoma[2]
- There remains a need for structured data from the real-world setting associated with epcoritamab treatment for patients with R/R DLBCL and R/R FL

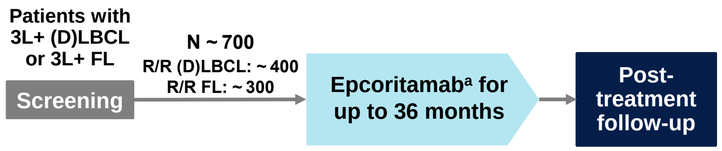
Here, we describe the study design for EpcoReal (NCT06830759), a prospective, observational multicenter trial evaluating outcomes and clinical treatment patterns in patients with 3L+ (D)LBCL or 3L+ FL treated with epcoritamab in the real-world setting

Figure 1. Epcoritamab Mechanism of Action



STUDY DESIGN

Figure 2. EpcoReal Study Design (NCT06830759)



[a]Treatment with epcoritamab should be administered in accordance with the approved local label in the participating country.
3L+, third line or later treatment; (D)LBCL, (diffuse) large B-cell lymphoma; FL, follicular lymphoma; R/R, relapsed/refractory.

Key Inclusion Criteria

- Age ≥ 18 years old
- Scheduled to be treated with epcoritamab for 3L+ (D)LBCL or 3L+ FL
- The decision to treat should be made by the clinician prior to and independently of any decision to approach the patient to participate in the study

Visits and Assessments

- Visits should occur as per routine clinical practice prior to the baseline visit
- The baseline visit will be the point of initiation of epcoritamab treatment; physician visits will be scheduled at months 3 and 6, and Q6M thereafter, with visit windows ± 4 weeks to align with routine clinical practice
  - A follow-up visit will be performed 3 months after observation completion/treatment discontinuation to collect safety, survival, and other information
- In addition to study endpoints, patients will be assessed for adverse events at each study visit through the follow-up visit

Trial Status and Enrollment

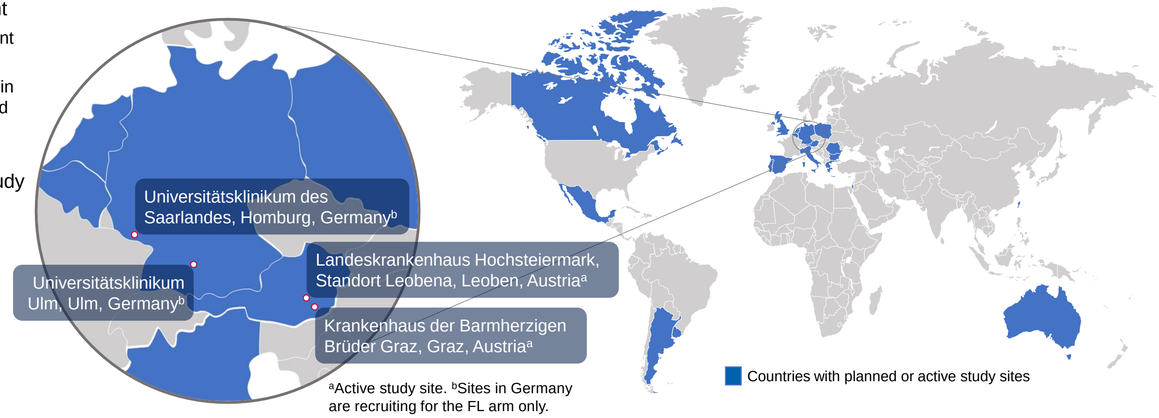
- The study is open for enrollment
  - Austria enrolled the first patient in March 2025
  - Approximately 80 study sites in ~ 12–20 countries are planned (**Figure 3**)
- As of October 11, 2025, 35 patients have enrolled in the study

Table 1. Study Endpoints

Primary Endpoint[a]
• ORR
Key Secondary Endpoints[a]
• DOR, DOCR
• CRR
• PFS
• TTP
• TTR
• OS
• TTNT
Exploratory Endpoints
• Changes in QoL as measured by the FACT-Lym and EORTC-QLQ-C30
• Number and duration of disease-related and all-cause hospitalizations
• Treatment patterns including prior lines of therapy (CAR T, transplant, or other systemic therapy), duration of each prior line of therapy, response to each prior line of therapy, reason for discontinuation or change, and choice of next therapy after epcoritamab

[a]Per Lugano 2014 criteria as assessed by investigator apart from OS and TTNT.
CAR T, chimeric antigen receptor T-cell therapy; CRR, complete response rate; DOR, duration of response; DOCR, duration of complete response; EORTC QLQ-C30, EORTC Core Quality of Life Questionnaire; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; QoL, quality of life; TTNT, time to next treatment; TTP, time to progression; TTR, time to response.

Figure 3. Countries With Planned or Active EpcoReal Enrollment Sites



[a]Active study site. [b]Sites in Germany are recruiting for the FL arm only.

SUPPLEMENTAL MATERIALS
Trial contact and enrollment information

Study site	City, Country	PI
Krankenhaus der Barmherzigen Brüder Graz[a]	Graz, Austria	Daniel Maria Mayer, MD
Landeskrankenhaus Hochsteiermark, Standort Leoben[a]	Leoben, Austria	Thamer Sliwa, MD
Universitätsklinikum des Saarlandes[b]	Homburg, Germany	Jörg Bittenbring, MD
Universitätsklinikum Ulm[b]	Ulm, Germany	Christian Buske, MD*

*Denotes study principal investigator for the country. [a]Active study site. [b]Sites in Germany are recruiting for the follicular lymphoma arm of the study only.