EPCORE™ DLBCL-4

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The EPCORE DLBCL-4 Research Study

An Overview for Healthcare Professionals

The information contained in this download is intended for healthcare providers only. This is not to be used with potential participants.

About the EPCORE DLBCL-4 Study

The EPCORE DLBCL-4 Study is a Phase 3, open-label study for adults with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL). The purpose of this research study is to evaluate the safety and efficacy of a study drug in combination with another antineoplastic agent (lenalidomide) compared to standard-of-care treatment (R-GemOx) or the study drug alone for adults with R/R DLBCL.

Objectives of the EPCORE DLBCL-4 Study

The primary and secondary objectives of the EPCORE DLBCL-4 Study include:

- To evaluate whether E-Len (epcoritamab plus lenalidomide) can improve outcomes as measured by progression-free survival (PFS) versus R-GemOx (rituximab plus gemcitabine and oxaliplatin) in R/R DLBCL
- To evaluate whether E-Len can improve outcomes as measured by the following versus R-GemOx in R/R DLBCL:
  - Complete Response Rate (CRR) determined by Lugano 2014 criteria, as assessed by an independent review committee (IRC)
  - Overall survival (OS)
  - Minimal residual disease (MRD) negativity rate

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Your patients may be eligible if they meet the following criteria:

- Are 18 years of age or older
- Have acceptable organ (renal, liver, and hematologic) function within the screening period prior to the first dose of study drugs
- Have histologically confirmed CD20+ DLBCL documented in their most recent representative pathology report
- Have R/R DLBCL and have received at least 1 prior systemic anti-lymphoma therapy (an anti-CD20 therapy must have been included in a prior line)
- Have relapsed/progressed after, or are ineligible for or unable to receive, CAR-T therapy or autologous stem cell transplant
- Have at least 1 target lesion defined as a measurable nodal lesion (long axis > 1.5 cm) or ≥ 1 measurable extra-nodal lesion (long axis > 1.0 cm) on CT scan or MRI and ^{18}F-FDG PET-positive on PET-CT scan

The EPCORE DLBCL-4 Study at a Glance

When discussing this clinical research study with your patients, here are some highlights to mention:

- The EPCORE DLBCL-4 Study is examining a study drug (epcoritamab) in combination with another anti-lymphoma agent (lenalidomide) as a potential way to improve outcomes compared to standard-of-care regimens alone in the treatment of R/R DLBCL.
- Epcoritamab is a liquid solution injected subcutaneously.
- Lenalidomide is a capsule taken orally.
- R-GemOx is a combination of drugs delivered through intravenous (IV) injection.
- Participants will be randomly assigned to one of three groups to receive epcoritamab alone or in combination with lenalidomide or R-GemOx alone.

- Participants in Groups A and C will have 4–5 study visits in the first 3 cycles then 1 visit per cycle until the end of study treatment. Participants in Group B will have 4 total cycles with 2 visits per cycle.
- All participants will go through 28-day cycles with their assigned study drugs. Total study duration will depend on each participant's response to their assigned study drugs and may last 1–2 years or more.
- If they qualify for and agree to participate in the study, study participants will not have to pay for the study drugs.
- Participation also includes regularly scheduled study visits for tests and procedures, as well as follow-up periods.

EPCORE DLBCL-4 Study Design

The EPCORE DLBCL-4 Study is divided into the following parts:

Screening	Potential participants will meet with the study team to determine if they are eligible to participate in the research study.
Study Treatment Period	This phase is designed to assess the initial safety and efficacy of epcoritamab in combination with lenalidomide. Participants will receive their assigned study drugs in 28-day cycles.
Follow-Up Periods	○ Safety Follow-Up: Participants will have a safety follow-up visit 60 days after their last dose of study drugs. ○ Post-Treatment Follow-Up: Participants will have visits every 8 weeks (±7 days) up to Week 24, every 12 weeks (±7 days) between Week 24 and Week 48, and every 24 weeks (±14 days) from Week 72 until disease progression. ○ Long-Term Follow-Up: Participants will have additional follow-up visits every 12 weeks.

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There are study clinics located throughout the world.

Find a location near you by visiting **EPCORE-trials.com/locations**.

If you have a patient with R/R DLBCL who may be a candidate, speak to them about the possibility of participating in this research study. Have your patients visit EPCORE-trials.com/DLBCL-4 to see if they are eligible and to learn more about the EPCORE DLBCL-4 Study.

This research study is evaluating the safety and efficacy of an approved drug for a specific investigational use that is currently not approved by regulatory health authorities.