EPCORE™ DLBCL-2
M20-621

The EPCORE DLBCL-2 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-2 Study

The EPCORE DLBCL-2 Study is a Phase 3, open-label study for adults with newly diagnosed diffuse large B-cell lymphoma (DLBCL). The purpose of this study is to evaluate the safety and efficacy of an investigational drug (epcoritamab) in combination with rituximab, cyclophosphamide, doxorubicin HCL, vincristine, and prednisone (R-CHOP) compared to R-CHOP alone.

- Epcoritamab is a humanized, IgG1-bispecific antibody targeting CD3+ T-cells and CD20+ B-cells; the mechanism of action is engagement of T-cells as effector cells to induce killing of CD20-expressing B-cells and tumor cells
- Epcoritamab is administered via subcutaneous injection

Objectives of the EPCORE DLBCL-2 Study

The objectives of the EPCORE DLBCL-2 Study include the following:

- To evaluate whether the addition of epcoritamab to 6 cycles of standard R-CHOP followed by 2 cycles of epcoritamab (E + R-CHOP) can prolong progression-free survival (PFS) compared with 6 cycles of standard R-CHOP followed by 2 cycles of rituximab (R-CHOP) in adults with newly diagnosed DLBCL
- To evaluate whether E + R-CHOP compared to R-CHOP can improve clinical outcomes as measured by the following key secondary endpoints:
  - Event-free survival (EFS), defined as the duration from randomization to the date of any of the following (whichever occurs first):
    - Disease progression, determined by Lugano criteria, as assessed by the IRC
    - Initiation of any non-protocol-specified new anti-lymphoma therapy for any reason
    - Death
  - CR rate on or after treatment completion by fluorodeoxyglucose positron emission tomography (FDG-PET), determined by Lugano criteria, as assessed by the IRC
  - OS, defined as time from randomization until death due to any causes
  - MRD negativity

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

- Are at least 18 years old and no more than 79 years old, with a life expectancy of ≥ 12 months
- Have newly diagnosed, histologically confirmed CD20+ DLBCL (de novo or histologically transformed from a diagnosis of follicular lymphoma) at most recent representative tumor biopsy based on the pathology report, with a World Health Organization (WHO) 2016 classification and including:
  - DLBCL, not otherwise specified (NOS)
  - High-grade B-cell lymphoma with MYC and BCL-2 and/or BCL-6 rearrangement with DLBCL morphology
  - T-cell/histiocyte-rich large B-cell lymphoma
  - Epstein-Barr virus–positive DLBCL, NOS
  - Follicular lymphoma Grade 3b
- Have no history of prior systemic anti-lymphoma therapy for DLBCL (including any definitive radiotherapy with curative intent)
- If histologically transformed from follicular lymphoma (FL), must not have previously been treated with > 1 lines of therapy for FL and must not have had an anthracycline-containing regimen or a CD3-CD20 bispecific antibody

Key Exclusion Criteria

- Have evidence of primary central nervous system (CNS) tumor or known CNS involvement at screening
- Have known active bacterial, viral, fungal, mycobacterial, parasitic, or other infection
- Have current autoimmune disease requiring immunosuppressive therapy except for up to 20 mg prednisone daily or equivalent

Additional eligibility criteria will be assessed by the study team.

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The EPCORE DLBCL-2 Study at a Glance

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

- The EPCORE DLBCL-2 Study is examining an investigational drug (epcoritamab) in combination with standard-of-care drugs as a potential way to improve outcomes compared to standard-of-care drugs alone in the treatment of DLBCL
- Epcoritamab is injected subcutaneously
- The study treatment period may last up to about 24 weeks (8 x 21-day cycles), depending on how well the study drugs work for participants
  - Total study duration will depend on each participant's response to their assigned study drugs
- If they qualify for and agree to participate in the study, study participants will not have to pay for the investigational drug
- Participation also includes regularly scheduled study visits for tests and procedures, as well as post-treatment follow-up

EPCORE DLBCL-2 Study Design

The EPCORE DLBCL-2 Study is divided into the following periods:

Screening Period (28 days)	Potential participants will meet with the study team to determine if they are eligible to participate in the study.
Study Treatment Period (24 weeks)	Participants who meet entry criteria will be randomized in a 2:1 ratio to one of the following study treatment groups: - Group A: Epcoritamab + R-CHOP - Group B: R-CHOP
Post-Treatment Follow-Up Period (varies)	Follow-up visits after study treatment will be approximately every 3 months for 2 years, then every 6 months for 2.5 years, then yearly. The total study duration will depend on each participant's response to their assigned study drugs.

Epcoritamab, the investigational drug being studied in patients with DLBCL, is under clinical development and is not approved for use by regulatory health authorities. Safety and efficacy are under evaluation.

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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 newly diagnosed 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/for-healthcare-providers] to see If they are eligible and to learn more about the EPCORE DLBCL-2 Study.