EPCORE™ NHL-6
M23-362

The EPCORE NHL-6 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 NHL-6 Study

The EPCORE NHL-6 Study (NCT 05451810) is a Phase 2, open-label study to evaluate the safety of epcoritamab monotherapy in adults with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) and classic follicular lymphoma (cFL) when administered in an outpatient setting.

- 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 NHL-6 Study

The objectives of the EPCORE NHL-6 Study include the following:

Primary objective:

- To evaluate the safety of epcoritamab monotherapy without mandatory hospitalization for the first full dose of epcoritamab in participants with R/R DLBCL who have received at least 1 prior line of systemic anti-lymphoma therapy including at least 1 anti-CD20 monoclonal antibody-containing therapy or R/R cFL who have received at least 2 prior lines of systemic anti-lymphoma therapies including at least 1 anti-CD20 monoclonal antibody-containing therapy

Secondary objective:

- A preliminary assessment for overall safety and efficacy of monotherapy of epcoritamab in an outpatient setting

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

18+

Are adult males or females, at least 18 years old, with a life expectancy > 3 months on standard of care (SOC) treatment

Have a diagnosis of R/R DLBCL or R/R cFL, with documented CD20+ mature B-cell neoplasm according to the 5th edition of the World Health Organization (WHO) Classification of Haematolymphoid Tumours based on representative and most recent pathology report

- Have R/R disease and have received at least 2 prior systemic antineoplastic therapies (for cFL participants) or at least 1 prior systemic antineoplastic therapy (for DLBCL participants) including at least 1 anti-CD20 monoclonal antibody-containing therapy
- And can include patients with “double-hit” or “triple-hit” DLBCL (technically classified in WHO 2016 as HGBCL, with MYC and BCL2 and/or BCL6 translocations)
  Note: Other double-/triple-hit lymphomas are not eligible

Have at least one target lesion defined as:

- ≥ 1 measurable nodal lesion (long axis > 1.5 cm and short axis > 1.0 cm) and/or ≥ 1 measurable extranodal lesion (long axis > 1.0 cm) on computerized tomography (CT) (or magnetic resonance imaging [MRI]) AND
- FDG positron emission tomography (PET) scan demonstrating positive lesion(s) compatible with CT (or MRI) defined anatomical tumor sites

Have Eastern Cooperative Oncology Group (ECOG) performance status 0 to 2

Have adequate organ function

Key Exclusion Criteria

- Have evidence of primary central nervous system (CNS) lymphoma or known CNS involvement by lymphoma at screening
- Have had an autologous stem cell transplant or CAR-T therapy within 100 days prior to the first dose of the study drug
  - Participants who are refractory to prior CAR-T therapy can receive first dose of study drug no fewer than 30 days from time of CAR-T therapy
- Have clinically significant cardiovascular disease, including the following:
  - Myocardial infarction within 1 year or stroke within 6 months prior to randomization

    OR
  - The following conditions prior to the first dose of the study drug:
    - unstable or uncontrolled disease/condition related to or affecting cardiac function (e.g., unstable angina, congestive heart failure, New York Heart Association Class III-IV)
    - uncontrolled cardiac arrhythmia, or other clinically significant ECG abnormalities in the opinion of the investigator
- Have known active bacterial, viral, fungal, mycobacterial, parasitic, or other infection
- Have no uncontrolled Human Immunodeficiency Virus (HIV) infection
  - HIV viral load that is undetectable and controlled with medication for at least 1 year prior to enrollment is allowed; CD4 count must be ≥ 350 cells/µl and serum HIV viral load < lower limit of detection for at least 1 year prior to enrollment

Additional eligibility criteria will be assessed by the study team.

The EPCORE NHL-6 Study at a Glance

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

- The EPCORE NHL-6 Study is examining an investigational drug (epcoritamab) for adults with R/R DLBCL or R/R cFL
- Epcoritamab is a liquid solution injected subcutaneously
- Total study duration for each participant will depend on their response to the study drug
- If they qualify for and agree to participate in the study, study participants will not have to pay for the investigational drug
- All participants will go through various 28-day cycles with their study drug
- Participation also includes regularly scheduled study visits for tests and procedures, as well as a long-term follow-up

EPCORE NHL-6 Study Design

The EPCORE NHL-6 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 (varies)	Participants who meet entry criteria will receive study treatment in cycles
Post-Treatment Follow-Up Period (varies)	○ Safety Follow-Up: Visit occurs about 60 days after the last study treatment ○ Survival Follow-Up: Visits occur every 12 weeks after the last clinical study visit

To find participating clinics, visit: EPCORE-trials.com/locations.

If you have a patient with R/R DLBCL or R/R cFL who may be a candidate, speak to them about the possibility of participating in this research study. Have your patients visit EPCORE-trials.com/NHL-6 to see if they are eligible and to learn more about the EPCORE NHL-6 Study.

This study is investigating the use of epcoritamab in the outpatient setting, currently not approved by the FDA. Safety and effectiveness of this investigational use is under evaluation.