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 follicular lymphoma (FL) Grade 1–3a 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 or R/R FL Grade 1-3a 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 18 years of age or older

Have a diagnosis of R/R DLBCL or R/R FL Grade 1-3a, with documented CD20+ mature B-cell neoplasm according to WHO classification 2016 or WHO classification 2008 based on representative pathology report

- Have R/R disease and were previously treated with at least 2 prior systemic antineoplastic therapies 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 one or more measurable disease sites:

- Fluorodeoxyglucose (FDG)-avid lymphomas: Measurable disease with computerized tomography (CT) (or magnetic resonance imaging [MRI]) scan with involvement of 2 or more clearly demarcated lesions/nodes with a long axis > 1.5 cm and short axis > 1.0 cm (or 1 clearly demarcated lesion/node with a long axis > 2.0 cm and short axis ≥ 1.0 cm) AND FDG positron emission tomography (PET) scan demonstrating positive lesion(s) compatible with CT (or MRI) defined anatomical tumor sites
- FDG-nonavid lymphomas: Measurable disease with CT (or MRI) scan with involvement of 2 or more clearly demarcated lesions/nodes with a long axis > 1.5 cm and short axis > 1.0 cm or 1 clearly demarcated lesion/node with a long axis > 2.0 cm and short axis ≥ 1.0 cm

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) tumor or known CNS involvement 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
- 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 within 3 months 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

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 FL
- 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 FL 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.

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