EPCORE™ NHL-5

M22-132

The EPCORE NHL-5 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-5 Study

The purpose of the EPCORE NHL-5 research study, which is a Phase 1b/2, open-label, multinational, multicenter, interventional study, is to evaluate the safety, tolerability, and preliminary efficacy of epcoritamab in combination with other antineoplastic agents in adults diagnosed with non-Hodgkin lymphoma (NHL).

- 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-5 Study

The objectives of the EPCORE NHL-5 Study include the following:

Primary objectives:

- To characterize the safety, toxicity, and tolerability profiles of epcoritamab when co-administered with antineoplastic agents in adults with B-cell NHL
- To determine the recommended dose for further investigation of epcoritamab when co-administered with anti-neoplastic agents in adults with B-cell NHL

Secondary objectives:

- To evaluate the anti-NHL activity of epcoritamab when given in combination with anti-neoplastic agents in adults with B-cell NHL
- To characterize the pharmacokinetics of epcoritamab when given in combination with anti-neoplastic agents in adults with B-cell NHL

EPCORE™ NHL-5
M22-132

Key Eligibility Criteria

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

18+ Are at least 18 years old

Have a diagnosis of one of the following:

- DLBCL (de novo or histologically transformed from follicular lymphoma or nodal marginal zone lymphoma) with histologically confirmed CD20+ disease at most recent representative tumor biopsy pathology report, inclusive of the following according to WHO 2016 classification and documented in pathology report:
  - DLBCL, not otherwise specified (NOS)
  - High-grade B-cell lymphoma with MYC and BCL-2 and/or BCL-6 translocations per WHO 2016 ("double-hit" or "triple-hit")

    Note: High-grade B-cell lymphomas NOS or other double-/triple-hit lymphomas (with histologies not consistent with DLBCL) are not eligible
- Follicular lymphoma (FL) Grade 3b
- FL with histologically confirmed CD20+ Grade 1 to 3a FL and no evidence of histologic transformation to an aggressive lymphoma at most recent representative tumor biopsy pathology report according to WHO 2016 classification
- Mantle cell lymphoma with histologically confirmed CD20+ disease at most recent representative tumor biopsy pathology report according to the WHO 2016 classification with evidence of overexpression of cyclin D1 in association with relevant markers or evidence of t(11;14) assessed by flow cytometry, FISH, or PCR
  - A report from the local laboratory is acceptable if available; if unavailable, a tumor block or slides must be sent to the central pathology laboratory for confirmation

Have 1 or more measurable disease sites:

- A positron emission tomography/computed tomography (PET-CT) scan demonstrating PET-positive lesion(s)
  AND
- At least 1 measurable nodal lesion (long axis > 1.5 cm) or ≥ 1 measurable extra-nodal lesion (long axis > 1.0 cm) on CT scan or MRI

EPCORE NHL-5
M22-132

What will happen during the EPCORE NHL-5 Study?

During the study, the primary investigational drug will be taken in combination with other antineoplastic agents for B-cell NHL. There is no placebo in this study, which means all participants will receive study treatment.

- All participants will go through 21-day, 28-day, or 56-day cycles with their study drugs
- Total study duration will depend on the participant's response to the study drugs
- Participation also includes regularly scheduled study visits for tests and procedures, as well as a long-term follow-up

There are multiple study treatment groups, or arms, for this study. Eligible participants will be assigned to a group depending on their disease.

EPCORE NHL-5 Study Design

The EPCORE NHL-5 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 study.
Dose Escalation Phase	This phase is designed to assess the initial safety and tolerability of epcoritamab in combination with other antineoplastic agents.
Expansion Phase	This phase is used to evaluate the safety, tolerability, and preliminary clinical activity of the recommended dose of epcoritamab in combination with antineoplastic agents.
Post-Study Treatment Follow-Up	All participants who complete their assigned study treatment will have post-study treatment follow-up visits that will occur in alignment with the post-study treatment scan schedule for each study arm.
Safety Follow-Up	All adverse events, serious adverse events (SAEs), and concomitant medications will be captured from the time of study drug administration through the safety follow-up period or until the participant begins new antilymphoma therapy, whichever comes first.
Survival Follow-Up	Survival follow-up will continue until death, withdrawal of the participant, the participant is lost to follow-up, study discontinuation, or study termination.

Epcoritamab is not approved for the use being investigated in this study. Safety and efficacy have not been established for this investigational use.

EPCORE™ NHL-5

M22-132

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 NHL 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-5 to see if they are eligible and to learn more about the EPCORE NHL-5 Study.