EPCORE™ FL-1
M20-638

The EPCORE FL-1 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 FL-1 Study

The EPCORE FL-1 Study is a Phase 3, open-label study for adults with relapsed or refractory follicular lymphoma (R/R FL). The purpose of this study is to evaluate the efficacy, safety, and tolerability of an investigational drug (epcoritamab) in combination with rituximab and lenalidomide (R^2) compared to R^2 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 FL-1 Study

The objectives of the EPCORE FL-1 Study include the following:

Primary objective:

- To evaluate the efficacy, safety, and tolerability of epcoritamab in combination with R^2 compared to R^2 alone in patients with R/R FL

Secondary objectives:

- To evaluate whether epcoritamab in combination with R^2 compared to R^2 alone can improve clinical outcomes as measured by key secondary endpoints (including CR, best overall response [BOR], overall survival [OS], and minimal residual disease [MRD] negativity) in patients with R/R FL

EPCORE™ FL-1
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Your patients may be eligible if they meet the following criteria:

- 18+ Are 18 years of age or older
- Have histologically confirmed Grade 1 to 3a FL stage II, III, or IV with no evidence of histologic transformation to an aggressive lymphoma and CD20+ at most recent representative tumor biopsy
- Have relapsed/refractory disease to at least one prior regimen that contained an anti-CD20 monoclonal antibody in combination with another anti-lymphoma agent(s) (those who received only prior anti-CD20 antibody monotherapy are not eligible)
- Have one or more measurable disease sites:
  - Fluorodeoxyglucose-positron emission tomography (FDG-PET) scan demonstrating positive lesion compatible with CT or MRI-defined anatomical tumor sites **AND**
  - ≥ 1 measurable nodal lesion (long axis ≥ 1.5 cm and short axis > 1.0 cm) or ≥ 1 measurable extra-nodal lesion (long axis ≥ 1.0 cm) on CT scan or MRI
- Have Eastern Cooperative Oncology Group (ECOG) performance status 0 to 2

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
- Are refractory to lenalidomide
- Have prior bispecific antibody targeting CD3 and CD20

Additional eligibility criteria will be assessed by the study team.

EPCORE™ FL-1
M20-638

The EPCORE FL-1 Study at a Glance

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

- The EPCORE FL-1 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 follicular lymphoma
- Epcoritamab is a liquid solution injected subcutaneously
- The study treatment period is approximately 1 year, with follow-up visits every 16 weeks through year 2, then every 6 months through year 4, and yearly thereafter
  - Total study duration for each participant will depend on their response to the 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
- All participants will go through 28-day cycles with their study drugs
- Participation also includes regularly scheduled study visits for tests and procedures, as well as a long-term follow-up

EPCORE FL-1 Study Design

The EPCORE FL-1 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 (12 months)	Participants who meet entry criteria will be randomized in a 1:1:1 ratio to one of the following study treatment groups: - Arm A: R^2 + epcoritamab high dose - Arm B: R^2 + epcoritamab low dose - Arm C: R^2
Post-Treatment Follow-Up Period (varies)	Visits occur every 16 weeks up to 2 years from randomization, every 6 months for the following 2 years, and yearly thereafter.

This investigational drug being studied in FL patients is under clinical development and is not approved for use by regulatory health authorities. Safety and effficacy 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 relapsed or refractory follicular lymphoma who may be a candidate, speak to them about the possibility of participating in this research study.