EPCORE™ PEDS-1

M20-429

The EPCORE PEDS-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 shared with potential participants.

About the EPCORE PEDS-1 Study

The purpose of the EPCORE PEDS-1 research study, which is a global Phase 1b, single-arm study, is to evaluate the safety and PK profile of epcoritamab monotherapy in pediatric patients (and young adults) with relapsed/refractory Burkitt's or Burkitt-like lymphoma/leukemia, DLBCL, or other aggressive mature (CD20+) B-cell lymphomas who have failed to reach remission with re-induction therapy or who are unable to receive further consolidation with cell therapy.

- 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
- Epcoritamab is administered via subcutaneous injection

Objectives of the EPCORE PEDS-1 Study

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

Primary objective:

- To evaluate the safety and PK profile of epcoritamab monotherapy in pediatric participants (and young adults) with relapsed/refractory Burkitt's or Burkitt-like lymphoma/leukemia, DLBCL, or other aggressive mature (CD20+) B-cell lymphomas who have failed to reach remission with re-induction therapy or who are unable to receive further consolidation with cell therapy

Secondary objective:

- To evaluate the preliminary efficacy and immunogenicity of epcoritamab monotherapy

Key Eligibility Criteria

Your patients may be eligible if they meet the following criteria (please refer to the protocol for a full list of eligibility criteria):

Were at least 1 and under 18 years old at the time of primary diagnosis

- Patients up to 25 years old with a diagnosis of Burkitt's or Burkitt-like lymphoma/leukemia are also eligible

Have a histologically confirmed CD20+ mature B-cell neoplasm according to WHO classification or WHO classification 2008:

- DLBCL – de novo or transformed
- Burkitt's or Burkitt-like lymphoma/leukemia
- Other aggressive mature B-cell lymphomas

Patients with relapsed or primary refractory disease (as above) meeting any of the following criteria:

- Progressive disease at any time during or after second-line chemoimmunotherapy (CIT)
- Best response of stable disease (SD) after a minimum of 2 cycles of second-line CIT
- Best response of partial response (PR) after a minimum of 3 cycles of second-line CIT
- CR after a minimum of 3 cycles of second-line CIT therapy but unfit or ineligible for consolidation with cell therapy
- Not in CR and unable to initiate or tolerate (i.e., must discontinue) second-line CIT
- Cell therapy (allogeneic or autologous transplant or CAR-T therapy) received as consolidation, but CR was not obtained or maintained

What will happen during the EPCORE PEDS-1 Study?

In this study, the investigational drug will be studied as monotherapy. Participants will receive the investigational drug in a step-up dosing regime, and dosing will be based on weight categories. There is no placebo in this study.

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

The investigational drug will be administered as a subcutaneous (SC) injection in a step-up dosing regime:

- Cycle 1: Priming (Day 1), intermediate (Day 8), and 2 full doses (Day 15 and Day 22)
- Cycle 2–3: Full dose weekly
- Cycle 4–9: Full doses every 2 weeks
- Cycle 10 onward: Full doses every 4 weeks

EPCORE PEDS-1 Study Design

The EPCORE PEDS-1 Study is divided into the following periods:

Screening	Potential participants will meet with the study team to determine if they are eligible to participate in the study.
Study Treatment	The investigational drug will be dosed based on weight categories.
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 anti-lymphoma therapy, whichever comes first.
Response Follow-Up	Participants who have discontinued study treatment for reasons other than progressive disease will continue study follow-up visits according to the disease assessments schedule at the pre-specified intervals.
Survival Follow-Up	Survival follow-up will continue every 12 weeks until death, full withdrawal of the participant's consent, the participant is lost to follow-up, study discontinuation, or study termination.

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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 pediatric patient with mature B-cell 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/PEDS-1 to see if they are eligible and to learn more about the EPCORE PEDS-1 Study.

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