The pivotal TRANSFORM trial (NCT03575351) is a global, randomized, open-label, parallel group multicenter Phase 3 study evaluating lisocabtagene maraleucel (liso-cel) head to head against the current standard therapy for high risk, relapsed or refractory large B-cell lymphoma (LBCL) after failure of first-line therapy in adults who are refractory or relapsing <12 months and potential candidates for hematopoietic stem cell transplant.1

For more information, visit clinicaltrials.gov.

TRANSFORM clinical trial fact sheet

About the trial
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Unmet need in LBCL
Non-Hodgkin lymphoma (NHL) is a cancer that starts in white blood cells called lymphocytes. LBCL is a type of NHL.2

Overview
184 transplant eligible adults with high-risk, relapsed or refractory LBCL were randomized 1:1 to receive standard therapy consisting of salvage chemotherapy followed by HDT + ASCT.

Key eligibility
• LBCL, including: diffuse large B-cell lymphoma (DLBCL) not otherwise specified, follicular lymphoma grade 3B, primary mediastinal LBCL, T-cell/histiocyte-rich LBCL, high grade B-cell lymphoma, double-hit lymphoma/triple-hit lymphoma histologically confirmed
• PET-positive per Lugano criteria
• Age ≥18 and ≤75 years
• ECOG ≤1
• Refractory or relapsed within 12 months after anthracycline/anti-CD20 containing first-line therapy
• Eligible for HDT + ASCT

The patient-centric trial allowed for crossover from the standard therapy arm to the liso-cel arm upon:
• Failure to achieve a complete or partial response by nine weeks post-randomization (after three cycles of salvage therapy)
• Disease progression
• Need to start new antineoplastic therapy due to efficacy concerns

Bridging chemotherapy was permitted in the liso-cel arm for disease control.

Primary endpoint
Event-free survival, defined as time from randomization to death from any cause, progressive disease, failure to achieve a response by nine weeks post-randomization or start of new antineoplastic therapy due to efficacy concerns

Key secondary endpoints
• Complete response rate
• Progression-free survival
• Overall survival

Sites
50+ study locations across the United States, Europe and Japan

Our cell therapy clinical development programs are evaluating therapies with the potential to transform the treatment landscape in blood cancer.

We are committed to advancing our cell therapy research to identify and move quickly on promising therapies that science shows will provide benefit for patients in need across a wide spectrum of blood cancers and solid tumors.

REFERENCES: