Bristol Myers Squibb™

TRANSFORM clinical trial fact sheet

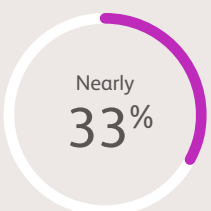
About the trial

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.

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]



of all NHL cases are LBCLs.[3]

of patients with LBCL have relapsed or refractory disease after chemotherapy-containing regimens.[4]

An intensive hospital-based regimen of salvage chemotherapy followed by high-dose chemotherapy (HDT) + autologous stem cell transplant (ASCT) has been the second-line standard of care for nearly 30 years.[5] However, only an estimated 25% of transplant eligible patients proceed to receive stem cell transplant and experience long-term clinical benefit, leaving an unmet need.[5]

TRANSFORM study design[1]

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.

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.

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

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

Bristol Myers Squibb's research in cell therapy

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.

BMS is committed to advancing cell therapy research and transforming patients' lives through science.

REFERENCES:
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4. Sawalha, Y. Relapsed/Refractory Diffuse Large B-Cell Lymphoma: A Look at the Approved and Emerging Therapies. *Journal of personalized medicine. 11* (12), 1345.
5. Kondo, E. Autologous Hematopoietic Stem Cell Transplantation for Diffuse Large B-Cell Lymphoma. *Journal of clinical and experimental hematopathology* : JCEH, 56(2), 100–108.