Miltenyi Biomedicine

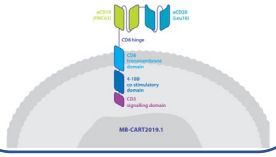
DALY EU

DALY 2-EU

A pivotal Phase II randomised, multi-centre, open-label study to evaluate the efficacy and safety of MB-CART2019.1 compared to standard of care therapy in participants with relapsed/refractory diffuse large B-cell lymphoma (R-R DLBCL), who are not eligible for high-dose chemotherapy and autologous stem cell transplantation (EudraCT 2020-003908-14) [1]

DALY 2-EU specifically addresses the elderly high risk patient population **and assesses the status of early CAR T-cell treatment as a curative option in** non transplant eligible patients

MB-CART2019.1
Zamtocabtagene



- Unique tandem CAR T product targeting CD19 and CD20
- Is a FRESH CAR T cell product with 15 days needle-to-needle time
- Phase I data shows low incidence of CRS/ICANS[2]

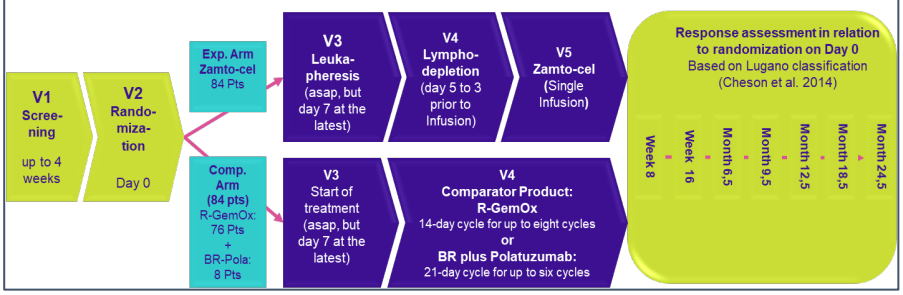
Study facts

Primary endpoint: PFS
Sample Size: 168 patients
Participating sites: >45 centers in 10 European countries
Trial design: randomized Phase II
Treatment:

- 84 patients treated with 2.5 x 10^6 MB-CART2019.1 (Zamtocabtagene autoleucel)
- 84 patients treated with Standard of Care
  - 76 patients with R-Gemcitabine/Oxaliplatin
  - 8 patients with R-Bendamustin/Polatuzumab

If you have a potential patient – please contact your DALY 2-EU trial site!

Zamtocabtagene in 2nd line DLBCL in Europe
Schematic Overview



Key inclusion criteria

- ≥18 years
- R/R disease within 1 year after first-line (anthracycline and rituximab containing first-line therapy regimen)
- Histologically proven DLBCL and associated subtypes (DHL, THL, PMBCL, tFL), according to the WHO 2016 classification:
- Deemed ineligible to receive autoSCT and HDC based on physician assessment and meeting specific criteria:
- Either: Age ≥ 18 years and
  - Prior ASCT (as first-line consolidation) or
  - Haematopoietic Cell Transplantation-specific Comorbidity Index (HCT-CI) > 3.
- or: Age ≥ 65 years and at least 1 of the criteria below:
  - Impaired cardiac function (left ventricular ejection fraction (LVEF) < 50%), or
  - Impaired renal function (creatinine clearance [CrCl] < 60 mL/min) as determined by the MDRD (Modification of Diet in Renal Disease) formula, or
  - Impaired pulmonary function (diffusing capacity for carbon monoxide or forced expiratory volume in 1 second of 66% to 80%) or dyspnoea on slight activity, or
  - ECOG > 1.

Inclusion and exclusion criteria may vary according to country;
aSCT, autologous stem cell transplantation; vedotin; CAR, chimeric antigen receptor; CD, cluster of differentiation; DLBCL, diffuse large B cell lymphoma; ECOG, Eastern Cooperative Oncology Group R/R, relapsed/refractory; WHO, World Health Organization

Registered at: ClinicalTrials.gov. NCT04844866. https://clinicaltrials.gov/ct2/show/NCT04844866. Accessed 17 November 2021; **2.** Miltenyi Biomedicine. Data on file, 2021