patients must be <18 years of age, weight ≥6 kg, and have confirmed B-NHL relapsed or refractory to ≥1 prior lines of therapy. Karnofsky (age ≥16 years) or Lansky (age <16 years) performance status must be ≥60. Patients must not have active central nervous system disease involvement before infusion or prior treatment with any anti-CD19 or gene therapy. Prior therapy can include systemic therapies and allogeneic or autologous hematopoietic stem cell transplant (HSCT) provided it occurred >3 months prior to screening. The primary endpoint of this study is overall response rate by International Pediatric NHL Response Criteria and Lugano 2014 criteria. Secondary outcomes include duration of response, event-free survival, relapse-free survival, progression-free survival, overall survival, pharmacokinetics, immunogenicity, frequency of post-tisagenlecleucel SCT, and biomarkers. Estimated enrollment for this study is 35 patients (at least 26 infused and evaluable).

Clinical trial information: NCT03610724.

Keywords: CD19; non-Hodgkin lymphoma (NHL).

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OT13
ELARA: A PHASE 2 TRIAL INVESTIGATING THE EFFICACY AND SAFETY OF TISAGENLECLEUCEL IN ADULT PATIENTS WITH REFRACTORY/RELAPSED FOLLICULAR LYMPHOMA

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Background: Tisagenlecleucel is an anti-CD19 chimeric antigen receptor-T cell (CAR-T) therapy that was approved in 2017 for the treatment of pediatric and young adult patients up to 25 years of age with relapsed/refractory (r/r) B-cell acute lymphoblastic leukemia (Maude et al. *NEJM*. 2018), as well as for the treatment of adult patients with r/r diffuse large B-cell lymphoma in 2018 (Schuster et al. *NEJM*. 2018). Follicular lymphoma (FL) is the second most common non-Hodgkin lymphoma in the Western hemisphere, with limited treatment options in patients refractory to or relapsing after standard therapies. In a phase 2a study of patients with r/r CD19+ lymphomas, 10 of 14 (71%) patients with r/r FL treated with tisagenlecleucel achieved a durable complete remission at a median follow-up of 28.6 months (Schuster et al. *NEJM*. 2017). Here we introduce ELARA (NCT03568461), a phase 2 study evaluating the efficacy and safety of tisagenlecleucel in patients with r/r FL.

Methods: ELARA is a phase 2, single-arm, multicenter, open label trial. Eligible patients must be ≥18 years of age, have radiographically measurable grade 1, 2, or 3A FL that is refractory to a second or later line of systemic therapy (including an anti-CD20 antibody and an alkylator), or relapsed within 6 months after completion of a second or later line of systemic therapy, or relapsed during anti-CD20 antibody maintenance (following ≥2 lines of therapy as above) or within 6 months after maintenance completion, or relapsed after autologous hematopoietic stem cell transplant (HSCT). Patients with central nervous system involvement, or those who received prior anti-CD19 therapy, gene therapy, adoptive T-cell therapy, or allogeneic HSCT are not eligible. The primary endpoint of this study is complete response rate based on Lugano classification response criteria. Secondary outcomes include overall response rate, duration of response, overall survival, cellular kinetics, immunogenicity, safety, and patient-reported outcomes. Estimated enrollment for this study is 113 patients. The study is currently open to patient enrollment.

Clinical trial information: NCT03568461.

Keywords: CD19; follicular lymphoma (FL).

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OT14
PORTIA: A PHASE 1B STUDY EVALUATING SAFETY AND EFFICACY OF TISAGENLECLEUCEL AND PEMBROLIZUMAB IN PATIENTS WITH RELAPSED/REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA

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Background: Tisagenlecleucel is an anti-CD19 chimeric antigen receptor-T cell therapy approved for pediatric patients with r/r B-cell acute lymphoblastic leukemia in 2017 (Maude et al. *NEJM*. 2018) and adult patients with relapsed/refractory diffuse large B-cell lymphoma (r/r DLBCL) in 2018 (Schuster et al. *NEJM*. 2018). The JULIET trial showed efficacy and safety of tisagenlecleucel in r/r DLBCL; subgroup analyses suggested an association between PD-1/PD-L1 interaction and lack of response (Agoulnik et al. EHA. 2018). Pembrolizumab after tisagenlecleucel has shown clinical activity in r/r DLBCL (Chong et al. *Blood*. 2017). We introduce PORTIA, a trial investigating safety and efficacy of tisagenlecleucel plus pembrolizumab in r/r DLBCL.

Methods: PORTIA is a phase 1b, multicenter, open-label, dose-timing and dose-expansion trial. Optimal timing of pembrolizumab administration will be based on the estimation of probability of dose-limiting toxicities (DLTs). A 2-parameter Bayesian Logistic Regression Method guided by the Escalation with Overdose Control principle will guide dose-timing selection together with review of accumulating safety and cellular kinetic data. Eligible patients must be ≥18 years old and have a confirmed diagnosis of r/r DLBCL with measurable disease and no active central nervous system disease; received ≥2 prior lines of therapy, including anti-CD20 and anthracycline-based chemotherapy, relapsing to or not eligible for autologous stem cell transplant (SCT); ECOG performance status must be 0 or 1. Patients treated with prior allogeneic SCT or anti-CD3, anti-CD19, or checkpoint inhibitor therapy are excluded. Primary endpoints are the proportion of patients receiving pembrolizumab per protocol schedule, the incidence of DLTs in the dose-timing selection phase, and overall response rate in the dose-expansion phase. Secondary outcomes include duration of response, progression-free survival, overall survival, safety, cellular kinetics, and immunogenicity. Estimated enrollment is 8-12 patients in the dose-timing and 12-16 patients in the dose-expansion phase. Dose-timing selection is currently ongoing. The first cohort of 4 patients receiving pembrolizumab at day 15 after tisagenlecleucel infusion has been completed.

Clinical trial information: NCT03630159.

Keywords: CD19; diffuse large B-cell lymphoma (DLBCL); Pembrolizumab.

Disclosures: Jaeger, U: Honoraria: *Novartis*, *AbbVie*, *Bioverativ*, *Celgene*, *Gilead*, *Janssen*, *MSD*, *Roche*, *Takeda Millennium*, *Amgen*, *AOP Orphan*, *BMS*, *Sandoz*; Research Funding: *Novartis*, *Bioverativ*, *Celgene*, *Gilead*, *Janssen*, *Roche*; Other Remuneration: *Novartis*, *AbbVie*, *Celgene*, *Gilead*, *Janssen*, *MSD*, *Roche*, *Takeda Millenium*, *Amgen*, *APO Orphan*, *BMS*, *Sandoz*. **McGuirk, J:** Honoraria: *Kite Pharma*; Research Funding: *Novartis*, *Kite Pharma*, *Fresenius Biotech*, *Astellas Pharma*, *Bellicum Pharmaceuticals*, *Gamida Cell*, *Pluristem Ltd*. **Worel, N:** Honoraria: *Novartis*. **Riedell, P:** Honoraria: *Kite Pharma*, *Bayer*, *Novartis*, *Verastem*. **Fleury, I:** Honoraria: *Gilead*, *Novartis*, *Roche*, *Seattle Genetics*, *Janssen*, *AbbVie*. **Borchmann, P:** Honoraria: *Novartis*. **Forcina, A:** Employment Leadership Position: *Novartis*. **Chu, J:** Employment Leadership Position: *Novartis*. **Leung, M:** Employment Leadership Position: *Novartis*. **Pacaud, L:** Employment Leadership Position: *Novartis*. **Waller, E:** Stock Ownership: *Cambium Medical Technologies*, *Cambium Oncology*, *Cerus Corporation*, *Chimerix*; Honoraria: *Cambium Medical Technologies*, *Kalytera*, *Novartis*; Research Funding: *Celldex*, *Novartis*, *Pharmacyclics*; Other Remuneration: *Pharmacyclics*.

OT15
MULTI-CENTER PHASE II STUDY OF ORAL AZACITIDINE (CC-486) PLUS CHOP AS INITIAL TREATMENT FOR PERIPHERAL T-CELL LYMPHOMA

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