Abstract TPS7074: A randomized, open-label study of the efficacy and safety of galinpepimut-S (GPS) maintenance monotherapy compared to investigator's choice of best available therapy (BAT) in patients with acute myeloid leukemia (AML) who have achieved complete remission (CR) after second-line salvage therapy.

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BACKGROUND

- Patients with relapse/refractory (r/r) AML have poor outcomes and allogeneic stem cell transplantation (allo-SCT) can potentially cure some patients with r/r AML in second CR (CR2). However, barriers to transplantation such as advanced age, poor functional status, comorbidities or lack of donor availability exist and not all patients are able to proceed to allo-SCT. Therefore, novel strategies to decrease relapse risk in these patients are urgently needed.
- A National Cancer Institute consensus study on prioritization of cancer antigens ranked the Wilms tumor 1 (WT1) protein as the top immunotherapy target in cancer. WT1 has emerged as an encouraging vaccine target in AML due to its overexpression in leukemic blasts.
- Maintenance therapy with galinpepimut-S (GPS), a multivalent heteroclitic WT1 peptide vaccine, has shown promising activity in patients with AML by inducing a strong innate immune response (CD4+/CD8+) against the WT1 antigen and across a broad range of HLA types.

METHODS

- This is an open-label, multicenter, randomized, phase III study of GPS vs. BAT in patients with AML in CR2/CRp2. The clinical trial is actively enrolling, and the registry number is NCT04229979.
- The primary endpoint of the study is overall survival (OS). Secondary endpoints include safety and tolerability of GPS and leukemia-free survival. Exploratory endpoints include WT1-specific immune response dynamics in blood and bone marrow.
- Approximately 125 - 140 patients will enroll, in a 1:1 ratio, to provide at least 90% power under an assumed hazard ratio of 0.636, based on median OS of 8.0 m (BAT) and 12.6m (GPS).
- Eligibility

Inclusion	Exclusion
- ≥18y with AML within 6m of achieving CR2/CRp2	-CNS involvement
- Ineligible for Allo-SCT	-Live vaccine within 30d prior to first GPS dose
- ≥300 lymphocytes/ul	-Having a diagnosis of immunodeficiency
- Adequate renal and hepatic function	-≥10mg daily of prednisone 7d prior to GPS dose
- ECOG 0-3	-Hypersensitivity to study agent

SCHEMA

AML in CR2 post-2nd line therapy in patients ≥ 18 yrs (incl. CRp2, but with adequate ANC and ALC counts)

Ineligible/unable to undergo Allo-SCT

N=125-140

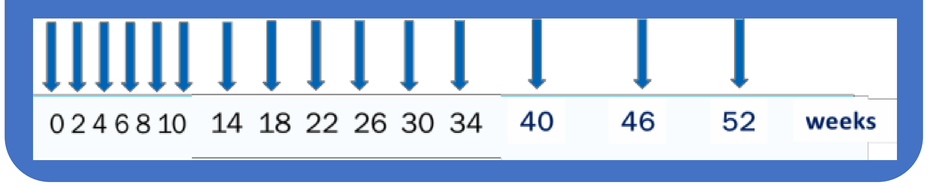
~30-50 centers (50:50 US/EU)

Stratification axes:

- CR2 vs CRp2 status
- Cytogenetics risk category at initial diagnosis (poor vs other)
- Duration of historical CR1 (<12/>12 months)
- MRD status

1:1

Galinpepimut-S/Montanide/GM-CSF



Best Available Therapy (BAT):

- Observation
- LDAC +/- Ven
- HMA +/- Ven