Northside Hospital Cancer Institute

Immunotherapy Program

NH1334 PHASE 2b Clinical Trial

A Phase 2b, Open-label, Multicenter, Randomized Parallel-Group, Two-Stage, Study of an Immunotherapeutic Treatment, DPX-Survivac and Pembrolizumab with and without Intermittent Low-Dose Cyclophosphamide, in Subjects with Relapsed/Refractory Diffuse Large B-Cell Lymphoma.

Northside Hospital Cancer Institute Immunotherapy Program in collaboration with IMV Inc. is participating in a Phase 2b, Open-label, Multicenter, Randomized Parallel-Group, Two-Stage, Study of an Immunotherapeutic Treatment, DPX-Survivac and Pembrolizumab with and without Intermittent Low-Dose Cyclophosphamide, in Subjects with Relapsed/Refractory Diffuse Large B-Cell Lymphoma.

Primary Objectives:

- To determine the objective response rate (ORR) in each of the study arms.

Inclusion Criteria

- ECOG performance status of ≤ 1.Subjects with an ECOG performance status of 2 may be enrolled with Medical Monitor approval
- Progressive disease following at least two (2) lines of prior systemic therapy for DLBCL; prior treatment must have included an anthracycline and rituximab (or another CD20-targeted agent)
- Must be Autologous stem cell transplant or CAR-T ineligible as per Investigator's assessment

Exclusion Criteria

- Primary CNS lymphoma or active secondary CNS involvement and/or lymphomatous meningitis
- Autologous stem cell transplant within ˂100 days prior to D0
- Chimeric antigen receptor T cell (CAR-T) therapy within ˂28 days prior to D0
- The following prior medications/procedures are exclusionary.
    - a. Allogeneic stem cell transplant or solid organ transplant or allogeneic CAR-T
    - b. Prior therapy with anti-survivin therapy
    - c. Anti-PD-1, anti-PD-L1, anti-PD-L2, or CTLA-4 agent
    - d. Chronic systemic steroid therapy (>10 mg daily prednisone equivalent)
    - e. Prescribed or over-the-counter probiotic treatments
    - f. Live-attenuated vaccine within 30 days of planned start of study therapy
- History of (non-infectious) pneumonitis that required steroids or current pneumonitis

If you have any questions, would like to discuss study logistics, or the eligibility of any patients, please contact Stacey Brown, NH BMT/Leukemia Clinical Research Manager, at **404-780-7965** or **stacey.brown@northside.com**