NORTHSIDE HOSPITAL CANCER INSTITUTE

IMMUNOTHERAPY PROGRAM

NH1335 PHASE II Clinical Trial

A Phase II, Open-label, Multicenter Study of the Safety and Efficacy of TAK-007 in Adult Patients With Relapsed or Refractory B-cell Non-Hodgkin Lymphoma

Northside Hospital Cancer Institute Immunotherapy Program in collaboration with Takeda is participating in a Phase 2 open-label, multicenter study will investigate the safety and efficacy of TAK-007 administered intravenously (IV) in adult patients with relapsed/refractory B-cell NHL, including LBCL and iNHL who have failed ≥2 prior systemic therapies. Eligible patients are required to have previously received an anti-CD20 monoclonal antibody (mAb) and chemotherapy regimen.

Primary Objectives:

- To evaluate the safety and tolerability of TAK-007 in adult patients with relapsed/refractory B-cell NHL to determine the recommended phase 2 dose (RP2D).
- To evaluate the efficacy of TAK-007 in adult patients with relapsed/relapsed LBCL and iNHL measured by ORR

Secondary Objectives:

- To evaluate secondary efficacy endpoints (CR, DOR, PFS, and OS)
- To further evaluate the safety and tolerability of TAK-007 in adult patients with r/r LBCL and iNHL
- To characterize cellular kinetics (CK) of TAK-007
- To assess pharmacodynamics of TAK-007

Inclusion Criteria

- ECOG 0-1
- Diagnosis of R/R CD19 expressing disease as follows:
    - DLBCL NOS
    - HGBL with MYC and BCL2 and/or BCL6 rearrangement
    - HGBL NOS without translocations
    - DLBCL arising from iNHL, including FL or MZL
    - T-cell/histocyte-rich LBCL
    - DLBCL associated with chronic inflammation
    - Epstein-Barr virus-positive DLBCL-NOS
    - Primary cutaneous DLBCL, leg type
    - PMBCL
    - FL Grade 3B
    - iNHL including FL grades 1, 2, 3A, MZL
- At least 2 prior lines of systemic therapy:
    - LBCL must have anti-CD20 mAb and anthracycline-containing regimen and ineligible for high-dose chemo or ASCT
    - iNHL must have an anti-CD20 mAb and an alkylating agent

Exclusion Criteria

- Primary or secondary CNS involvement by lymphoma, Burkitt Lymphoma, MCL, lymphoplasmocytic lymphoma, or transformed CLL/SLL (Richter')
- History of anti-CD19 therapy (including CAR-T or monoclonal antibodies)
- Autologous or Allogeneic transplant within 3 months of enrollment. Off of immunosuppressive therapy without evidence of GVHD
- History of DVT or PE within 6 months

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**