NORTHSIDE HOSPITAL CANCER INSTITUTE

IMMUNOTHERAPY PROGRAM

NH1332 PHASE II Clinical Trial

A Phase II Open-label Clinical Study to Evaluate the Efficacy and Safety of Zilovertamab Vedotin (MK-2140) in Participants With Relapsed or Refractory Diffuse Large B-Cell Lymphoma

Northside Hospital Cancer Institute Immunotherapy Program in collaboration with Merck is participating in a Phase 2 Open-label Clinical Study to evaluate the efficacy and safety of Zilovertamab Vedotin (MK-2140) in participants with relapsed or refractory Diffuse Large B-Cell Lymphoma. Participants must have received at least 2 or more lines of prior therapy, including multi-agent chemo immunotherapy that includes anti-CD20 monoclonal antibody, and have failed autologous stem cell transplant or are auto-SCT ineligible will be enrolled in this study.

Primary Objectives:

- To evaluate objective response rate per Lugano Response Criteria as assessed by blind independent central review (BICR).

Secondary Objectives:

- To evaluate duration of response per Lugano Response Criteria as assessed by BICR
- To evaluate the safety and tolerability of zilovertamab vedotin

Inclusion Criteria

- Relapsed or refractory DLBCL and have failed at least 2 lines of prior therapy, and have failed auto-SCT or are auto-SCT ineligible. Must have received prior rituximab/anti-CD20 monoclonal antibody.
    - a) Relapsed disease: disease progression after achieving an overall response of PR or CR in response to the most recent therapy.
    - Refractory disease: failure to achieve CR or PR to the most recent therapy.
- ECOG performance status of 0 to 2 assessed within 7 days before time of enrollment

Exclusion Criteria

- Prolongation of QTc interval (per Fridericia's formula) is >480 ms
- Known history of liver cirrhosis
- Has pericardial effusion or clinically significant pleural effusion
- Has baseline peripheral neuropathy> Grade 1
- Has a history of a second malignancy, unless potentially curative treatment has been completed with no evidence of malignancy for 2 years
- Transformed DLBCL from indolent lymphoma
- Prior allo-SCT, acute GVHD or ongoing evidence of chronic GVHD
- Has known active CNS lymphoma involvement or active CNS involvement by lymphoma

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**