NSH 1277

NORTHSIDE HOSPITAL CANCER INSTITUTE
IMMUNOTHERAPY PROGRAM

The Blood & Marrow Transplant Group OF GEORGIA

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PHASE I Clinical Trial Opening

For High-Risk Newly Diagnosed Multiple Myeloma Patients

Northside Hospital Cancer Institute Immunotherapy Program in collaboration with Celgene is opening a Phase I open-label, multi-center study to evaluate the safety of bb2121, a genetically modified autologous T-cell immunotherapy product, in subjects with high-risk (HR), newly diagnosed multiple myeloma (NDMM) (KarMMa-4).

This study will determine the optimal dose/safety of bb2121 in patients with NDMM with HR features defined by the Revised International Staging (R-ISS) Stage III (according to International Myeloma Working Group (IMWG) criteria 2016 at diagnosis.

Bb2121 is a genetically modified autologous T-cell immunotherapy product consisting of a T lymphocyte-enriched population that contains cells transduced with an anti-BCMA02 CAR lentiviral vector encoding a chimeric antigen receptor targeting BCMA.

BUILT TO BEAT CANCER

Primary Objective:

To evaluate the safety and to determine the optimal dose of bb2121 in patients with HR NDMM.

Inclusion Criteria:

- Newly diagnosed MM based on IMWG diagnostic criteria prior to initiating induction anti-myeloma therapy.
  - ISS Stage III and cytogenetic abnormalities with t(4;14) and/or del(17p); and/or t(14:16) by iFISH, OR
  - ISS Stage III and serum LDH >ULN
- Measurable disease:
  - M-protein: sPEP ≥0.5g/dL or uPEP ≥200mg/24 hours AND/OR
  - Light chain MM without measureable disease in serum or urine: serum immunoglobulin free light chain ≥10mg/dL (100mg/L) and abnormal serum immunoglobulin kappa lambda free light chain ratio
- Received ≤3 cycles of the following induction anti-myeloma therapy prior to enrollment:
  - Cycle 1: one of the following regimens (RVd, KRd, CyBorD, D-RVd and D-KRd)
  - Cycle 2 to Cycle 3: either KRd or RVd (Cycle 3 must be without dexamethasone)

Exclusion Criteria

- High-risk for developing DVT or PE and are unable or unwilling to undergo anti-thrombotic therapy.
- Peripheral neuropathy Grade 2 or higher.
- No history of prior malignancy within the last 5 years.
- Diagnosis of Plasma cell leukemia, Waldenstroms, POEMS, primary amyloidosis.
- Primary amyloidosis.

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**

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