
# NSH 1304

NORTHSIDE HOSPITAL CANCER INSTITUTE
IMMUNOTHERAPY PROGRAM

The Blood & Marrow Transplant Group
OF GEORGIA

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# Clinical Trial Opening

## For Relapsed/Refractory Multiple Myeloma Patients

Northside Hospital Cancer Institute Immunotherapy Program in collaboration with Bristol Myers Squib is participating in an open-label, multi-arm, multi-cohort, multi-center, Phase I/II study to determine the safety, tolerability, efficacy, PK of bb2121 in combination with other therapies in adult subjects with R/R MM. The study will consist of two parts: dose finding (Phase I) and dose expansion (Phase II). Dose expansion may occur in one or more arms.

**PRIMARY OBJECTIVES**

- Phase I – Evaluate safety and define the recommended Phase II dose (RP2D) and schedule of combination agents administered with bb2121 at the target dose of $450x10^6$ CAR+ T-cells in adult subjects with Relapsed/Refractory MM (R/R MM).
- Phase II – Evaluate efficacy of combination agents in adult subjects with R/R MM who received bb2121 at the target dose of 450x106 CAR+ T-cells defined as complete response rate (CRR).

**SECONDARY OBJECTIVES**

- Evaluate safety of combination agents in adult subjects with R/R MM who received bb2121 at the target dose of $450x10^6$ CAR+ T-cells.

BUILT TO BEAT CANCER

## Inclusion Criteria:

- Adults ≥18 years of age
- Diagnosis of MM with measurable disease
  - SPEP ≥0.5g/dLO
  - UPEP ≥200mg/24hr OR
  - Serum immunoglobulin free light chain ≥10mg/dLand abnormal serum immunoglobulin kappa/lambda ratio

***Received at least:***

- 3 prior MM regimens for Arm A Cohort 1 and Arm B (IMiD, proteasome inhibitor, anti-CD38Ab)
- 1-3 prior MM regimens for Arm A Cohort 2 and Arm C (IMiD)
- Evidence of PD during or within 6 months of completing last regimen
- Achieved minimal response to at least one (1) prior regimen
- ECOG 0-1

## Exclusion Criteria

- Non-secretory MM, history of or active plasma cell leukemia, Waldenstrom's macroglobulinemia, POEMS syndrome, amyloidosis
- Hgb <8g/dL, ANC <1.0, Plts <75, CrCl <45 (Arm A, cohort a & Arm C), ANC <1.5, Plts <100, CrCl <60 (Arm A cohort b/c & Arm B)
- Corrected serum calcium >13.5, AST/ALT >2
- FEV1 <50%, O2 Saturation <92%
- Prior malignancies that have been disease free for <5 years
- Autologous transplant within 12 weeks prior to leukapheresis (Arm A Cohort 1 and Arm B); within 12 months (Arm A Cohort 2 and Arm C)
- Peripheral neuropathy ≥Grade 2 within 14 days prior to leukapheresis

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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