

NSH 1216

  
NORTHSIDE HOSPITAL  
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IMMUNOTHERAPY PROGRAM

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## PHASE III Clinical Trial Opening

### For Relapsed/Refractory Multiple Myeloma Patients

Northside Hospital Cancer Institute Immunotherapy Program in collaboration with Celgene, is opening a Phase III, multi-center, randomized, open-label study to compare the efficacy and safety of bb2121 versus standard triplet regimens in subjects with relapsed and refractory multiple myeloma (rrMM) (KarMMa-3).

**PRIMARY OBJECTIVE:** Compare the efficacy of bb2121 to standard triplet regimens in subjects with relapsed and refractory multiple myeloma (rrMM) as measured by progression-free survival (PFS).

**SECONDARY OBJECTIVE:** Evaluate the safety of bb2121 compared to standard triplet regimens in subjects with rrMM.

 **BUILT TO BEAT CANCER**

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](mailto:stacey.brown@northside.com).

### RRMM

- 2 - 4 prior MM regimens
- Has received prior treatment with dara, PI and IMiD for  $\geq 2$  consecutive cycles
- Must be refractory to the last treatment regimen

### Randomization 2:1

#### Leukapheresis

Bridging therapy (optional)

#### Arm A: bb2121 (n= ~254)

- Flu 30 mg/m<sup>2</sup> IV 3 days
- Cy 300 mg/m<sup>2</sup> IV 3 days
- bb2121 single dose IV
  - Dose 150-450 x 10<sup>6</sup> CAR+ T-cells

#### Arm B: Standard triplet regimens per Investigator's discretion (n = ~127)

- DARA + POM + dex (DPd) OR
- DARA + BTZ+ dex (DVd) OR
- IXA + LEN + dex (IRd)



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#### Key Inclusion Criteria

- Received at  $\geq 2$  - 4 prior MM regimens.
- Received prior treatment with daratumumab, a proteasome inhibitor and an immunomodulatory compound containing regimen for at least 2 consecutive cycles.
- Refractory to the last treatment regimen.
- Achieved at least a minimal response to at least 1 prior treatment regimen.

#### Key Exclusion Criteria

- Active or history of plasma cell leukemia, Waldenstrom's macroglobulinemia, POEMS syndrome, or amyloidosis.
- COPD with a forced expiratory volume in 1 second (FEV1) 50% of predicted normal.
- Previous history of allogeneic hematopoietic stem cell transplantation, treatment with any gene therapy-based therapeutic for cancer, investigational cellular therapy for cancer, or BCMA targeted therapy.
- Subject has received autologous stem cell transplantation (ASCT) within 12 weeks prior to randomization.