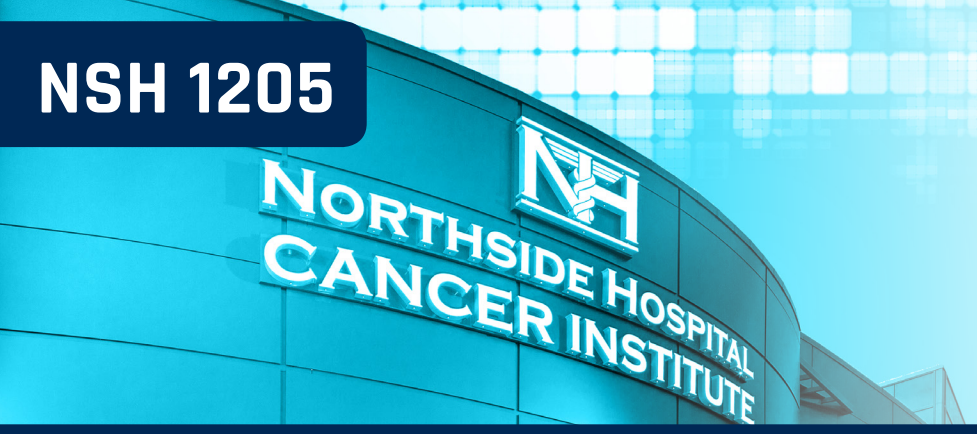


# NSH 1205

NORTHSIDE HOSPITAL CANCER INSTITUTE
IMMUNOTHERAPY PROGRAM

The Blood & Marrow Transplant Group
OF GEORGIA

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## PHASE II Clinical Trial Opening

### For Relapsed/Refractory Multiple Myeloma Patients

NH Immunotherapy Program in collaboration with GlaxoSmithKline is offering a Phase II, open label, two-arm randomized, multi-center study to evaluate the efficacy and safety of GSK2857916 in relapsed/refractory multiple myeloma patients who have received at least three prior lines of anti-myeloma therapy including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and who were previously treated with an antiCD38 antibody.

GSK2857916 is a humanized immunoglobulin G1 antibody-drug conjugate (ADC) which binds to B-cell maturation antigen, a target widely expressed on malignant multiple myeloma plasma cells.

BUILT TO BEAT CANCER

## PRIMARY OBJECTIVE

To evaluate the clinical efficacy of two different doses of GSK2857916 in participants with relapsed/refractory multiple myeloma.

## CRITERIA

| Select Inclusion Criteria | Select Exclusion Criteria |
|---|---|
| › Must have received an Auto-HCT (must be > 100 days and infection free post-transplant) or ineligible for TP | › Systemic anti-myeloma therapy within < 14 days or plasmapheresis within 7 days prior to the first dose study drug |
| › Must have failed at least 3 prior lines of anti-myeloma treatment including an anti-cd38 antibody alone or in combination and is refractory to an IMiD and to a proteasome inhibitor | › Known HIV infection. Presence of HBsAg or HBcAb, Positive HepCAb or positive HepC RNA |
| › Measurable disease with at least one of the following:<br>• Serum M-protein ≥ 0.5 g/dL (≥ 5g/L)<br>• Urine M Protein ≥ 200 mg/24h<br>• Serum FLC assay: Involved FLC level ≥ 10 mg/dL (≥100 mg/L) and an abnormal serum free light chain ratio (<0.26 or >1.65) | › Symptomatic amyloidosis, active POEMS syndrome, active plasma cell leukemia at the time of screening |
| | › Prior Allo HCT |
| | › Corneal epithelial disease |
| | › Investigational drug within 14 days or five half-lives |
| | › Prior monoclonal antibody therapy within 30 days of receiving the first dose of study drugs. |
| | › Prior BCMA target therapy |
| | › QTcF ≥ 470 msecs ,uncontrolled arrhythmias |
| › All prior treatment-related toxicities must be ≤ Grade 1 at the time of enrollment except alopecia and Grade 2 peripheral neuropathy | |

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**.

NORTHSIDE HOSPITAL
CANCER INSTITUTE
5670 Peachtree Dunwoody Road
Suite 1000
Atlanta, GA 30342