

**NSH 1224**

**NORTHSIDE HOSPITAL  
CANCER INSTITUTE**



**NORTHSIDE HOSPITAL  
CANCER INSTITUTE**  
IMMUNOTHERAPY PROGRAM

**The Blood & Marrow  
Transplant Group**  
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**PHASE I**

# **Clinical Trial Opening**

**For Relapsed/ Refractory Advanced Multiple Myeloma (MM) Patients**

Northside Cancer Institute Immunotherapy Program in collaboration with Pfizer, is opening a Phase I, open-label, multi-dose, multi-center, dose escalation, safety, PK and pharmacodynamics study of PF-06863135, a heterodimeric humanized full-length bispecific antibody comprised of one B-cell Maturation Antigen (BCMA) binding arm and one CD3 binding arm paired through hinge mutation technology.

**BUILT TO BEAT CANCER**

**This study will be divided into several parts:**

**Part 1** – Escalating doses of PF-06863135 administered IV (0.1, 0.3, 1, 3, 10, and 30 µg/kg).

**Part 2** – Dose expansion phase; schedule will be based on either Part 1 or Part 1a, depending on schedule from which MTD was declared. IV or SQ will be selected

### **CRITERIA**

#### **Inclusion**

##### **Relapsed/refractory MM with measureable disease**

- Serum M-protein  $\geq 1\text{g/dL}$
- Urine M-protein  $\geq 200\text{mg}/24\text{hrs}$
- If doesn't meet above, serum FLC  $\geq 10\text{mg/dL}$

##### **Received prior therapy that includes:**

- Proteasome inhibitor (Velcade, Kyprolis)
- iMiD drug (Revlimid, Pomalyst)
- anti-CD38 antibody (Dara, Empliciti)

#### **Exclusion**

- **Prior malignancies treated in the past 3 years**
- **Any immunodeficiency or autoimmune disorder**
- **History of Grade  $\geq 3$  immune-mediated adverse event considered related to prior immune-modulatory therapy**
- **Stem cell transplant within 100 days or DLI within 30 days of study enrollment**



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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**.