Safety and Tolerability of Allogeneic, Off-the-Shelf Placental Natural Killer Cells (PNK-007) in Phase 1 Multiple Myeloma (NCT02955550) and Acute Myeloid Leukemia (NCT02781467)

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INTRODUCTION

Background

• Natural Killer (NK) cells are innate immune cells which play an important role in host immune surveillance against pathogenic infection and cell transformation. Multiple studies extensively transplantaing NK cells in clinical settings have demonstrated the potential of NK cells to induce remissions for hematologic malignancies with a consistent safety profile.

• Celularity has developed a GMP procedure for generating Placental Hematopoietic Stem Cell Derived Natural Killer cells (PNK-007). This technology platform enables the scalable production of off-the-shelf, allogeneic NK cell therapy.

• PNK-007 is a fully allogeneic, off-the-shelf CD34+ derived NK cell product which is not genetically modified. Celularity has developed a GMP procedure for generating Placental Hematopoietic Stem Cell Derived Placental Natural Killer Cells (PNK-007). This technology platform enables the scalable production of off-the-shelf, allogeneic NK cell therapy.

Objective

To assess the safety and determine the feasibility of infusing PNK-007 at various doses and scheduling following ASCT in subjects with multiple myeloma.

Secondary:

To explore potential clinical efficacy at Day 90-100 post ASCT. Determine if rhIL-2 is needed and if so, the appropriate schedule.

AHL MELOID LEUKEMIA (AML) STUDY OBJECTIVES

• Primary:

To assess the safety and determine the maximal tolerated dose (MTD) of PNK-007.

Secondary:

To explore potential clinical efficacy.

PNK-007 manufacturing process overview

• Placental CD34+ cells were cultivated in the presence of cytokines including thrombopoietin (Tpo), stem cell factor (SCF), Flt3 ligand, IL-7, IL-15 and IL-2 for 35 days to generate PNK-007 under the cGMP standards followed by release testing.

• PNK-007 was >95% pure for CD56+/CD3- cells that exhibited in vitro cytotoxicity against K562 cells.

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• To assess the safety and determine the maximum tolerated dose (MTD) of PNK-007.

• To explore potential clinical efficacy by complete remission (CR) or CR with incomplete response (CRi) for PNK-007-AML-001 and PNK-007-MM-001 study design.

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