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 utilizing allogeneic NK cells (A-NK) have demonstrated the potential of NK cells to induce remissions for hematologic malignancies. Celularity has developed a proprietary GMP platform that enables the scalable production of off-the-shelf, allogeneic NK cell therapies. Using this technology platform, Celularity developed PNK-007, a Placenta Derived Natural Killer cell therapy.

PNK-007 shows cytotoxic activity against various cancer cell lines and secretes cytokines such as IFNγ during co-culture with cancer cells.

PNK-007 has been evaluated for the treatment of relapsed/refractory acute myeloid leukemia (AML) in a phase I study (PNK-007-AML-001). Here, we present final results of the Phase I study in multiple myelomas (MM) after autologous stem cell transplant (ASCT).

METHODS

Placental CD34+ cells were cultured in the presence of interleukin-3, antimetabolite (10NF), stem cell factor (SCF), PI3K ligand, IL-15 and IL-2 for 35 days to generate PNK-007 under the GMP standards followed by release testing.

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

RESULTS

INRODUCTION

Study Design
This was a Phase I, multicenter, open-label trial to study the dosing and timing of infusion of PNK-007 post ASCT in MM.

No subjects were undergoing or had completed (re)induction therapy for the purposes of ASCT for MM.

Two dose levels of PNK-007 have been evaluated: 10 x 106 cells/kg and 30 x 106 cells/kg.

All subjects were to receive treatment with rhIL-2, but later was amended to reduce to 5 days.

CONCLUSIONS

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ACKNOWLEDGEMENTS

DISCLOSURES

No subjects enrolled the initial dose level of 10 x 106 cells/kg. All 15 subjects received the higher dose level of 30 x 106 cells/kg.

No DLT were observed in the 28 days following PNK-007 infusion.

There were no DLT events observed in the 28 days following PNK-007 infusion.

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