Enrollment of Pediatric and Adolescent Patients with MAGE-A4+ Advanced Synovial Sarcoma into Cohort 2 of SPEARHEAD-1: A Phase 2 Trial of Afamitresgene Autoleucel (“Afami-cel” formerly ADP-A2M4)

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Introduction

• Afamitresgene autoleucel (“Afami-cel” formerly ADP-A2M4) is an autologous, specific peptide-enhanced affinity receptor (SPER) T cell therapy (Figure 1) targeting solid tumors expressing melanoma-associated antigen A4 (MAGE-A4) in human leukocyte antigen (HLA) A*02:01 eligible patients.

Rationale for SPEARHEAD-1 Cohort 2 Development

• Synovial sarcoma is the most common malignant nonhematopoietic sarcoma in those sarcoma in children and adolescents.1
• Few treatment options are available, especially for those who experience disease progression after frontline therapy.
• High unmet need for new pediatric therapeutics to treat advanced synovial sarcoma in the second-line setting.
• Patients aged 15 to 30 years with advanced synovial sarcoma, post-frontline systemic therapy, showed overall response rate (ORR) of 35.3% in Cohort 1 of SPEARHEAD-1 (Figure 2).
• ORR of afami-cel was higher than those historically reported for paclitaxel and trabectedin in the second-line systemic therapy setting.6

SPEARHEAD-1 Cohort 2 Trial Design

• Cohort 2 design is similar to Cohort 1 (Figure 3).
• HLA and MAGE-A4 screening is performed at a central laboratory using the same method as Cohort 1.
• All patients undergo apheresis, and their isolated T cells are transduced with the MAGE-A4+SPER T cells using a lentivector, followed by ex vivo expansion (Figure 4).
• Enrollment in Cohort 2 of SPEARHEAD-1 is now open, including 7 pediatric sites across the USA and France (Figure 2).

Figure 1. Specific Peptide-Enhanced Affinity Receptor T Cells

Figure 2. Response in Cohort 1 of SPEARHEAD-1 to Tumor Cells (Tumor Cell Count vs. ORR)

Figure 3. SPEARHEAD-1 Cohort 2 Trial Design

Figure 4. Patient Cell Journey

Figure 5. Locations of SPEARHEAD-1 Cohort 2 Trial Sites Across North America and Europe