

BLA STN: 125789

Applicant: Adaptimmune LLC

Submission Receipt Date: December 5, 2023

Action Due Date: August 1, 2024

Proper Name: afamitresgene autoleucel

Proprietary Name: TECELRA

Indication: TECELRA is a genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with unresectable or metastatic synovial sarcoma who have received prior systemic therapy, are positive for HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P, and negative for HLA-A*02:05P, and whose tumor expresses the MAGE-A4 antigen as detected by an FDA-approved test.

The following officers or employees of FDA participated in the decision to approve this application and consented to be identified on this list.

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