Products Approved in FY 2024: Regenerative Medical Products

Review Category	Approval Date	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification	Non-proprietary Name	Notes
Regenerative Medical Products	Jul. 31, 2024	Akuugo Suspension for Intracranial Implantation (SanBio Company Limited)	Conditional/Time-limited Approval	Human somatic stem cell-processed products	Vandefitemcel	This product is a cell suspension manufactured by introducing plasmid vectors encoding the human Notch-1 intracellular domain into bone marrow-derived mesenchymal stem cells that were collected from healthy adult donors and then cultured and separated/proliferated. The product is intended to be used for improvement of chronic motor paresis associated with traumatic brain injury by transplanting into the brain by stereotactic brain surgery. (Orphan regenerative medical product) (SAKIGAKE designation, Regenerative medical product)
Regenerative Medical Products	Aug. 16, 2024	Breyanzi Suspension for Intravenous Infusion (Bristol-Myers Squibb K.K.)	Change	Human somatic cell-processed products	Lisocabtagene maraleucel	The product is a regenerative medical product introduced with chimeric antigen receptor (CAR) that targets CD19 antigen by using a recombinant lentiviral vector for the CD4-positive and CD8-positive T cells derived from the patient's peripheral blood. This product was approved for the indications for the third- and further-line treatment in patients with relapsed or refractory large B-cell lymphoma and relapsed or refractory follicular lymphoma (Grade 3B) in March 2021. Also, the product was approved for the additional indications for the second-line treatment in patients with relapsed or refractory large B-cell lymphoma and relapsed or refractory follicular lymphoma (Grade 3B) in December 2022. The third- and further-line treatment in patients with relapsed or refractory follicular lymphoma (Grade 1, 2, 3A) and the second-line treatment in patients with relapsed or refractory high-risk follicular lymphoma (Grade 1, 2, 3A) were added to the indication of the product by this application. (Orphan regenerative medical product)