Products Approved in FY 2022: Regenerative Medical Products

Review Category	Approval Date	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification	Non-proprietary Name	Notes
Regenerative Medical Products	Aug. 26, 2022	Kymriah Suspension for Intravenous Infusion (Novartis Pharma K.K.)	Change	Human somatic cell-processed products	Tisagenlecleucel	The product is a human somatic cell-processed product composed of genetically modified T cells that are cultured and proliferated after introducing chimeric antigen receptor (CAR) that specifically recognizes CD19 antigen by using a lentiviral vector into the T cells derived from the patient's peripheral blood. The product was approved for the indications for relapsed or refractory B-cell acute lymphoblastic leukemia and relapsed or refractory diffuse large B-cell lymphoma in March 2019. Relapsed or refractory follicular lymphoma was added to the indication of the product by this application. [Orphan regenerative medical product]
Regenerative Medical Products	Sep. 26, 2022	Carvykti Suspension for Intravenous Infusion (Janssen Pharmaceutical K.K.)	Approval	Human somatic cell-processed products	Ciltacabtagene autoleucel	The product is a regenerative medical product introduced with chimeric antigen receptor (CAR) that specifically recognizes B-cell maturation antigen (BCMA) by using a recombinant lentivirus vector for the T cells derived from the patient's peripheral blood. It is administered as an intravenous drip into a vein and used for the treatment of relapsed or refractory multiple myeloma. [Orphan regenerative medical product]
Regenerative Medical Products	Dec. 20, 2022	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. The product was approved for the indications for relapsed or refractory large B-cell lymphoma and relapsed or refractory follicular lymphoma with at least 2 lines of prior chemotherapy in March 2021. Relapsed or refractory large B-cell lymphoma and relapsed or refractory follicular lymphoma with 1 line of prior chemotherapy were added to the indication of the product by this application. [Orphan regenerative medical product]
Regenerative Medical Products	Dec. 20, 2022	YESCARTA Intravenous Drip Infusion (Daiichi Sankyo Company, Limited)	Change	Human somatic cell-processed products	Axicabtagene ciloleucel	The product is a regenerative medical product introduced with chimeric antigen receptor (CAR) that specifically recognizes CD19 antigen by using a recombinant retrovirus vector for the T cells derived from the patient's peripheral blood. The product was approved for the indications for relapsed or refractory large B-cell lymphoma in patients who are eligible for autologous hematopoietic stem cell transplantation (HSCT) and have received 2 or more lines of prior therapy or in patients who are not ineligible for autologous HSCT and have received 1 or more lines of prior therapy in January 2021. Relapsed or refractory large B-cell lymphoma in patients who are eligible for HSCT and have received 1line of prior therapy was added by this application. [Orphan regenerative medical product]
Regenerative Medical Products	Mar. 17, 2023	JACEMIN (Japan Tissue Engineering Co., Ltd.)	Approval	Human somatic cell-processed products	Melanocyte-containing Human (Autologous) Epidermis-derived Cell Sheet	The product is an epidermis-derived cell sheet, which is produced by culturing the epidermal cells separated from patient-derived normal skin tissues and melanocytes into a sheet shape. The product is intended to be used for transplantation for vitiligo that is ineffective or not indicated for nonsurgical treatment after abrading the epidermis for the purpose of repigmentation by supplying epidermal cells containing melanocytes.

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Regenerative Medical Products	Mar. 17, 2023	Vyznova (Aurion Biotech Japan, LLC.)	Approval	Human somatic cell-processed products	Neltependocel	The product is a cell suspension composed of fully differentiated cultured human corneal endothelial cells prepared by culturing human (allogeneic) cornea-derived corneal endothelial cells separated from corneal tissue obtained from a human donor. The product is intended to be used for reconstructing damaged corneal endothelium monolayer tissue by transplanting into the anterior chamber in patients with bullous keratopathy. [Orphan regenerative medical product]