Products Approved in FY 2018: Regenerative Medical Products

Review Category	Approval Date	Brand Name (Applicant Company)	New Approval/ Partial Change	Classification	Non-proprietary Name	Notes
Regenerative Medical Products	Dec. 28, 2018	JACE (Japan Tissue Engineering Co., Ltd.)	Change	Human somatic cell-processed product	Human (autologous) epidermis-derived cell sheet	A product consisting of a human (autologous) epidermis-derived cell sheet (main component), which is produced using Green's technique, and a container (filled with tissue transport fluid) for transporting the patient's skin tissue to the manufacturing site (sub-component). To prepare the cell sheet, epidermal cells derived from a postage-stamp-sized piece of skin taken from the patient's own skin tissue are co-cultured with mouse embryo-derived 3T3-J2 feeder cells and formed into a sheet. The product has already been approved for the indications for cases of serious and extensive burns, and giant congenital melanocytic nevus. The application was submitted for the additional indications for the treatment of "dystrophic epidermolysis bullosa" and "junctional epidermolysis bullosa." (A "partial change" application) [Orphan regenerative medical products]
Regenerative Medical Products	Dec. 28, 2018	STEMIRAC Inj. (Nipro Corporation)	Conditional/ Time-limited Approval	Human somatic stem cell-processed products	Human (autologous) bone marrow-derived mesenchymal stem cell	A product consisting of human (autologous) bone marrow-derived mesenchymal stem cells (main component), and blood collection and bone marrow harvesting kits (sub-components). To prepare the main component, mesenchymal stem cells in bone marrow fluid taken from the patient are cultured and proliferated in vitro, and then cryopreserved. The sub-components are used for collecting the patient's peripheral blood and bone marrow fluid at medical institutions and for transporting these to the manufacturing site. The cultured bone marrow-derived mesenchymal stem cells are administered via intravenous infusion and used for treatment to improve neurological symptoms and functional disorders associated with spinal cord injury (only for use in patients with traumatic spinal cord injury and ASIA Impairment Scale A, B, or C). [SAKIGAKE designation, Regenerative medical products]
Regenerative Medical Products	Mar. 26, 2019	Kymriah Suspension for Intravenous Infusion (Novartis Pharma K.K.)	Approval	Human somatic cell-processed products	Tisagenlecleucel	The product is a human somatic cell-processed product composed of genetically modified autologous T cells which are cultured and proliferated after introducing chimeric antigen receptor (CAR) which specifically recognizes CD19 antigen using a lentiviral vector into the T cells derived from the patient's peripheral blood. It is given as a single infusion (drip) into a vein and used for the treatment of CD19-positive relapsed or refractory B-cell acute lymphoblastic leukemia (ALL) and CD19-positive relapsed or refractory diffuse large B-cell lymphoma (DLBCL). [Orphan regenerative medical products]
Gene Therapy Products	Mar. 26, 2019	Collategene Intramuscular Injection 4 mg (AnGes, Inc.)	Approval	Plasmid vector products	Beperminogene perplasmid	The product is an injection of plasmid vector composed of 5,181 base pair including cDNA which encodes human hepatocyte growth factor. It is administered intramuscularly to an ischemic site of the lower limb and used for the treatment of ulcers in patients with chronic arterial occlusion (arteriosclerosis obliterans and Burger's disease) who have not responded sufficiently to the standard drug therapy and are unable to undergo revascularization.