



List of Cell/Tissue/Gene Products with marketing authorization (MA) in Australia by TGA
(Therapeutic Goods Administration)

Name (MA Holder)	Product description and indication(s)	Product category	Date of MA	Current Status	Additional information
Kymriah (Novartis Pharmaceuticals Australia Pty Ltd)	CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of pediatric and young adult patients up to 25 years with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory, in relapse post-transplant or in second or later relapse and for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy	Gene Therapy Product	19-Dec-2018	Still in Market	Click Here for Link to TGA Website Click Here for Link to TGA Website
Chondrocytes - T - Ortho-ACI (Orthocell Pty Ltd)	Autologous cultured chondrocytes for use in treatment of cartilage lesions associated with the knee, patella and ankle	Cell Therapy Product	26-Mar-2017	Still in market	Click Here for Link to TGA Website
IMLYGIC (talimogene laherparepvec) (Amgen Australia Pty Ltd)	Oncolytic immunotherapy derived from a herpes simplex virus-1 genetically engineered to infect and replicate within melanoma cells and to produce GM-CSF for unresectable melanoma	Gene Therapy Product	6-Jun-2016	Still in market	Click Here for Link to TGA Website Click Here for Link to TGA Website

List of Cell/Tissue/Gene Products with MA in Canada by Health Canada (March 2018)

Name (MA Holder)	Product description and indication(s)	Product category	Date of MA	Current Status	Additional information
KYMRIAH (NOVARTIS PHARMACEUTICALS CANADA INC)	CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of pediatric and young adult patients 3 to 25 years with B-cell acute lymphoblastic leukemia (ALL) who are refractory, have relapsed after	Gene Therapy Product	05-Sept2018	In market	Click Here for Link to Health Canada Website

	allogeneic stem cell transplant (SCT) or are otherwise ineligible for SCT, or have experienced second or later relapse and for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma.				
Prochymal (MESOBLAST INTERNATIONAL SARL)	Allogeneic ex-vivo cultured adult human mesenchymal stem cells for the management of acute Graft versus Host Disease (aGvHD) in pediatric patients	Cell Therapy Product	02-May-2015	The product was never marketed in Canada	Click Here for Link to Health Canada Website

List of Cell/Tissue/Gene Products with MA in China by CSFDA (Chinese Food and Drug Administration)

Name (MA Holder)	Product description and indication(s)	Product category	Date of MA	Current Status	Additional information
Gendicine (Shenzhen SiBiono GeneTech Co. Ltd.)	Recombinant adenovirus expressing p53 for treatment of head and neck squamous cell carcinoma	Gene Therapy Product	Oct-2003	Still in market	Click Here

List of Cell/Tissue/Gene Products with MA in the European Union by European Medicines Agency (EMA) (updated September 2021)

Name (MA Holder)	Product description and indication(s)	ATMP	Date of MA	Current Status	Additional information
ABECMA (Celgene Europe BV)	Autologous B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell immunotherapy, for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies	GTMP	18-Aug-2021	Granted MA under conditional approval and additional monitoring	Click Here for Link to EMA Website
SKYSONA (bluebird bio [Netherlands] B.V.)	Genetically modified autologous bone marrow or blood CD34+ cells to contain a copy of the gene to make a functional ALDP to treat children under 18 years of age with early cerebral adrenoleukodystrophy	GTMP	16-Jul-2021	Granted MA under additional monitoring	Click Here for Link to EMA Website
LIBMELDY (Orchard Therapeutics)	Autologous CD34+ cell enriched population that contains hematopoietic stem and progenitor cells transduced ex vivo using a lentiviral vector encoding the human	GTMP	17-Dec-2020	Granted MA under additional monitoring	Click Here for Link to EMA Website

[Netherlands] B.V.)	arylsulfatase A gene intended for the treatment of children with metachromatic leukodystrophy				
TECARTUS (Kite Pharma EU B.V.)	Genetically modified autologous anti-CD19-transduced CD3+ cells intended for the treatment of relapsed or refractory mantle cell lymphoma	GTMP	14-Dec-2020	Granted MA under additional monitoring	Click Here for Link to EMA Website
ZOLGENSMA (AveXis EU Limited)	Adeno-associated virus vector-based gene therapy indicated for the treatment of babies and young children with spinal muscular atrophy (SMA) up to 21 kg with 5q SMA with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA Type 1; or for patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to three copies of the SMN2 gene	GTMP	18-May-2020	Granted MA under conditional approval and additional monitoring	Click Here for Link to EMA Website
ZYNTEGLO (bluebird bio [Netherlands] B.V.)	Autologous CD34+ cell enriched population that contains hematopoietic stem cells transduced with lentiglobin BB305 lentiviral vector encoding the beta-A-T87Q-globin gene for transfusion-dependent β -thalassaemia	GTMP	29-May-2019	Granted MA under conditional approval and additional monitoring	Click Here for Link to EMA Website
LUXTURN A (Spark Therapeutics Ireland Ltd.)	Adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy	GTMP	23-Nov-2018	Granted MA under additional monitoring	Click Here for Link to EMA Website
YESCARTA (Kite Pharma EU B.V.)	CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and primary mediastinal large B-cell lymphoma (PMBCL), after two or more lines of systemic therapy	GTMP	27-Aug-2018	Granted MA under additional monitoring	Click Here for Link to EMA Website
KYMRIAH (Novartis Europharm Limited)	CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of paediatric and young adult patients up to 25 years of age with B-cell acute lymphoblastic leukaemia (ALL) that is refractory, in relapse post-transplant or in second or later relapse, and for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy	GTMP	27-Aug-2018	Granted MA under additional monitoring	Click Here for Link to EMA Website
ALOFISEL (Takeda Pharma A/S)	Expanded allogeneic adipose stem cells as a suspension for injection for the treatment of complex perianal fistulas in patients with Crohn's disease	SCTMP	27-Mar-2018	Granted MA under additional monitoring	Click Here for Link to EMA Website
SPHEROX (CO.DON AG)	Spheroids of human autologous matrix-associated chondrocytes for knee repairing cartilage defects	TEP	10-Jul-2017	Granted MA under additional monitoring	Click Here for Link to EMA Website
STRIMVELIS (GSK Trading Services Limited)	Autologous CD34+ cells transduced with a retroviral vector that encodes for the human ADA cDNA sequence for severe combined immunodeficiency due to ADA deficiency	GTMP	26-May-2016	Granted MA under additional monitoring	Click Here for Link to EMA Website

IMLYGIC (Amgen Europe B.V.)	Oncolytic immunotherapy derived from a herpes simplex virus-1 genetically engineered to infect and replicate within melanoma cells and to produce GM-CSF for unresectable melanoma	GTMP	16-Dec-2015	Granted MA under additional monitoring	Click Here for Link to EMA Website
HOLOCLAR (Chiesi Farmaceutici S.p.A.)	Ex vivo expanded autologous human corneal epithelial cells containing stem cells for severe limbal stem cell deficiency	TEP	17-Feb-2015	Granted MA under conditional approval and additional monitoring	Click Here for Link to EMA Website

ATMP: Advanced Therapy Medicinal Product // **TEP:** Tissue Engineered Product // **GTMP:** Gene Therapy Medicinal Product // **SCTMP:** Somatic Cell Therapy Medicinal Product // **EC:** European Commission

List of Cell/Tissue/Gene Products with MA Withdrawn or Suspended in the European Union

Name (Manufacturer)	Product description and indication(s)	ATMP	Date of MA	Situation	Additional information
ZALMOXIS (MolMed SpA)	Donor's T lymphocytes genetically modified with a suicide gene as a control mechanism for GvHD after haploidentical Bone Marrow transplant	SCTMP	18-Aug-2016	Granted MA under conditional approval. Withdrawn: 9-Oct-2019. Requested by the company for commercial reasons	Click Here for Link to EMA Website
PROVENGE (Dendreon)	Autologous peripheral-blood mononuclear cells activated with prostatic acid phosphatase granulocyte-macrophage colony-stimulating factor for metastatic prostate cancer	SCTMP	6-Sep-2013	Granted MA under additional monitoring. Withdrawn: Company announced Bankruptcy in 2015	Click Here for Link to EMA Website
MACI (Aastrom)	Matrix applied characterised autologous cultured chondrocytes for repairing knee cartilage defects	TEP	27-Jun-2013	Granted MA under additional monitoring. MA suspended: 25-Sept-2014	Click Here for Link to EMA Website
GLYBERA (uniQure biopharma BV)	Alipogene tiparvovec (human lipoprotein lipase gene variant in a adeno-associated viral vector) for adult patients with familial lipoprotein lipase deficiency	GTMP	25-Oct-2012	Granted MA under additional monitoring. Withdrawn: MA expired on 25-Oct-2017. The company did not apply for renewal due to the lack of demand	Click Here for Link to EMA Website
CHONDROCELECT (TiGenix NV)	Characterised viable autologous cartilage cells expanded ex vivo for repairing knee cartilage defects	TEP	5-Oct-2009	The product was reimbursed in 3 countries. Withdrawn: 30-Nov-2016. Requested by the company for commercial reasons	Click Here for Link to EMA Website

MA: Marketing Authorisation // **ATMP:** Advanced Therapy Medicinal Product // **TEP:** Tissue Engineered Product // **GTMP:** Gene Therapy Medicinal Product // **SCTMP:** Somatic Cell Therapy Medicinal Product // **EC:** European Commission // **EMA:** European Medicines Agency

List of Cell/Tissue/Gene products with MA in India by Drug Controller General of India (DCGI)

Name (MA Holder)	Product description and indication(s)	Product category	Date of MA	Current Status	Additional information
CARTIGROW™ (Chondron ACI) (RMS Regrow)	Autologous cultured cartilage cells for treatment of articular cartilage defects	Cell Therapy Product	Apr-2017	Conditional approval, post market surveillance study required (50 subjects)	Click Here
OSSGROW™ (Ossron ABI) (RMS Regrow)	Autologous cultured osteoblasts for avascular necrosis of hip	Cell Therapy Product	Apr-2017	Conditional approval, post market surveillance study required (50 subjects)	
APCEDEN (APAC Biotech)	Autologous monocyte-derived mature dendritic cells for treatment of prostate, ovarian, colorectal and non-small cell lung carcinoma	Cell Therapy Product	Mar-2017	Conditional approval, post market surveillance study required	Click Here
Stempeucel® (Stempeutics Research)	Ex-vivo cultured adult allogeneic mesenchymal stromal cells for treatment of critical limb ischemia due to Thromboangiitis Obliterans (Buerger's disease)	Cell Therapy Product	May 2016	In market, limited release (200 patients on a cost recovery basis), post market surveillance study required	Click Here

List of Cell/Tissue/Gene products with MA in Japan by PMDA (Pharmaceuticals and Medical Devices Agency)

Name (MA Holder)	Product description and indication(s)	Product category	Date of MA	Current Status	Additional information (In Japanese)
KYMRIAH (tisagenlecleucel) (Novartis Pharmaceuticals Corporation)	CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of pediatric and young adult patients up to 25 years with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory, in relapse post-transplant or in second or later relapse and for the treatment of adult patients relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy	Gene Therapy Product	May 2019	In market	Click Here for Link to PMDA Website

Collategene (AnGes, Inc.)	DNA plasmid which encodes human Hepatocyte Growth Factor (HGF) gene for treatment of patients with critical limb ischemia (CLI)	Gene Therapy Product	March 2019	In market, conditional approval	Click Here for Link to PMDA Website
Stemirac	Expanded autologous mesenchymal stromal cells for treatment of spinal cord injury	Cell Therapy Product	December 2018	In market, conditional approval	Click Here for Link to PMDA Website
Temcell HS (JCR Pharmaceuticals Co. Ltd.)	Allogeneic mesenchymal stromal cells for treatment of acute graft versus host disease (aGVHD)	Cell Therapy Product	September 2015	In market	Click Here for Link to PMDA Website
HeartSheet (Terumo Corporation, Ltd.)	Autologous skeletal myoblast sheet product for the treatment of severe heart failure	Tissue Engineered Product	September 2015	Conditional approval	Click Here for Link to PMDA Website
JACC (J-TEC)	Autologous cultured cartilage	Tissue Engineered Product	July 2012	Still in market, previous authorization was as medical device	Click Here for Link to PMDA Website
JACE (J-TEC)	Autologous cultured epidermis for treatment of severe burns	Tissue Engineered Product	October 2007	Still in market, previous authorization was as medical device	Click Here for Link to PMDA Website

List of Cell/Tissue/Gene Products with MA in New Zealand by MEDSAFE (Medicines and Medical Devices Safety Authority)

Name (MA Holder)	Product description and indication(s)	Product category	Date of MA	Current Status	Additional information
Prochymal (Osiris Therapeutics Incorporated.)	Allogeneic ex-vivo cultured adult human mesenchymal stem cells indicated for the rescue of patients NLT 6 months to 17 years of age with acute graft versus host disease (aGvHD), refractory to treatment with systemic corticosteroid therapy or other immunosuppressive agents	Cell Therapy Product	14-Jun-2012	Approval lapsed	Click Here for Link to MEDSAFE Website

List of Cell/Tissue/Gene Products with MA in South Korea by MFDS (Ministry of Food and Drug Safety)

Name (MA Holder)	Product description and indication(s)	Product category	Date of MA	Current Status	Additional information
Rosmir® (Tego Science, Inc)	Injectable autologous fibroblasts for improvement of nasojugal groove (a.k.a. tear trough)	Cell Therapy Product	27-Dec-2017	Still in market	Click Here for Link to MFDS Website
INVOSSA®-K (Kolon Life Science, Inc.)	Non-transduced and retrovirally transduced allogeneic chondrocytes to overexpress Transforming Growth Factor-β1 (TGF-β1) in 3:1 ratio for treatment of moderate knee osteoarthritis (Kellgren & Lawrence grade 3)	Gene Therapy Product	12-Jul-2017	License revoked on 28-May-2019	Click Here for Link to MFDS Website
KeraHeal-Allo™ (Biosolution Co., Ltd.)	Composite cell product (allogeneic skin-derived keratinocytes suspended in a thermosensitive hydrogel) for deep 2nd degree burns	Cell Therapy Product	16-Oct-2015	Still in market	Click Here for Link to MFDS Website
NEURONATA-R® (Corestem, Inc.)	Autologous bone marrow mesenchymal stem cell therapy for Amyotrophic Lateral Sclerosis	Cell Therapy Product	30-Jul-2014	Orphan product	Click Here for Link to MFDS Website
Cupistem® (Anterogen)	Autologous adipose tissue-derived mesenchymal stem cell for Crohn's fistula	Cell Therapy Product	18-Jan-2012	Covered by insurance as of January 2014, orphan product	Click Here for Link to MFDS Website
CARTISTEM® (Medipost Co., Ltd.)	Human Umbilical Cord Blood-derived Mesenchymal Stem Cells for the treatment of knee articular cartilage defects in patients with osteoarthritis (ICRS grade IV)	Cell Therapy Product	18-Jan-2012	Still in market	Click Here for Link to MFDS Website
Cellgram®-AMI (Pharmicell Co., Ltd.)	Autologous Bone Marrow-derived Mesenchymal Stem Cells for Acute Myocardial Infarction patients (improvement of LVEF(Left Ventricular Ejection Fraction))	Cell Therapy Product	1-Jul-2011	Name at time of approval was Hearticellgram®-AMI, still in market	Click Here for Link to MFDS Website
CureSkin Inj. (S.Biomedics Co., Ltd.)	Autologous dermal fibroblasts (Depressed acne scar)	Cell Therapy Product	11-May-2010	Still in market	Click Here for Link to MFDS Website
Queencell® (Anterogen)	Autologous adipose tissue-derived adipose cell by minimal manipulation for subcutaneous tissue defect	Cell Therapy Product	26-Mar-2010	Still in market	Click Here for Link to MFDS Website

Kaloderm® (Tego Science, Inc)	Allogeneic keratinocytes (cell sheet) for deep 2nd degree burn or diabetic foot ulcer	Tissue Engineered Product	21-Mar-2005 (2nd degree burn) 24-Jun-2010 (Diabetic foot ulcer)	Still in market	Click Here for Link to MFDS Website
RMS Ossron™ (Sewon Cellontech Co., Ltd.)	Cultured Autologous Osteoblasts for focal bone formation, can be used with or without fibrin glue	Cell Therapy Product	26-Aug-2009	Still in market	Click Here for Link to MFDS Website
Immuncell-LC (GC Cell Corp.)	Autologous activated T-cell for liver cancer (hepatocellular carcinoma)	Cell Therapy Product	6-Aug-2007	Currently in market for hepatocellular carcinoma and in clinical trials for newly diagnosed glioblastoma (Phase III, completed) advanced pancreatic cancer (Phase II, completed) Received tentative approval in 2007 and product manufacture license as export product in 2013 from MFDS.	Click Here for Link to MFDS Website
CreaVax-RCC® (JW CreaGene Corporation)	Autologous Dendritic Cells for Metastatic Renal Cell Carcinoma	Cell Therapy Product	15-May-2007	Received tentative approval in 2007 and product manufacture license as export product in 2013 from MFDS.	Click Here for Link to MFDS Website
KeraHeal® (Biosolution Co., Ltd.)	Autologous skin-derived keratinocytes for deep 2nd degree burns that cover more than 30% of TBSA and 3rd degree burns that cover more than 10% of TBSA	Cell Therapy Product	3-May-2006	Still in market	Click Here for Link to MFDS Website
Holoderm® (Tego Science, Inc)	Autologous keratinocytes for deep 2nd degree burns that cover more than 30% of TBSA and 3rd degree burns that cover more than 10% of TBSA	Tissue Engineered Product	10-Dec-2002	Still in market, reimbursed by insurance	Click Here for Link to MFDS Website
Chondron™ (Sewon Cellontech Co., Ltd.)	Cultured Autologous Chondrocytes for focal cartilage defect of knee, can be used with or without fibrin glue	Cell Therapy Product	30-Jan-2001	Still in market	Click Here for Link to MFDS Website

List of Cell/Tissue/Gene products with MA in Switzerland by Swissmedic

Name (MA Holder)	Product description and indication(s)	Product category	Date of MA	Current Status	Additional information
Yescarta (Gilead Sciences Switzerland Sàrl)	CD19-directed genetically modified autologous T cell immunotherapy	Gene Therapy Product	17-Apr-2019	Still in Market	Click Here for Link to Swissmedic website

	indicated for the treatment of adult patients with relapsed or refractory DLBCL and PMBCL, after two or more lines of systemic therapy				
Spheriox (co.don schweiz GmbH)	Spheroids of human autologous matrix-associated chondrocytes for knee-repairing cartilage defects	Tissue Engineered Product	27-Mar-2019	Still in market	Click Here for Link to Swissmedic website
Alofisel (Takeda Pharma AG)	Expanded allogeneic adipose stem cells as a suspension for injection for the treatment of Crohn's associated complex perianal fistulas in adult patients with non-active or mild-grade Crohn's disease	Cell Therapy Product	27-Dec-2018	Still in market	Click Here for Link to Swissmedic website
Kymriah (Novartis Pharma)	CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of pediatric and young adult patients up to 25 y of age with B-cell ALL that is refractory, in relapse post-transplantation or in second or later relapse, and for the treatment of adult patients with relapsed or refractory DLBCL after two or more lines of systemic therapy	Gene Therapy Product	18-Oct-2018	Still in Market	Click Here for Link to Swissmedic website
Novocart 3D (B. Braun Medical)	Surgical therapy for the biological reconstruction of articular cartilage defects of the knee joint by means of carrier-coupled autologous cartilage cell transplantation (ATC).	Tissue Engineered Product	2-Oct-2014	Still in Market	Click Here for Link to Swissmedic website

List of Cell/Tissue/Gene Products with MA in the United States by US-FDA (United States Food and Drug Administration)

Name (MA Holder)	Product description and indication(s)	Product category	Date of MA	Current Status	Additional information
ZOLGENSMA (AveXis, Inc)	Gene therapy product for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene.	Gene Therapy Product	24-May-2019	Still in market	Click Here for Link to FDA Website
HPC, Cord Blood (MD Anderson Cord Blood Bank)	For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment	Cell Therapy Product	06-Jun-2018	Still in market	Click Here for Link to FDA Website
LUXTURNA (voretigene neparvovec-rzyl) (Spark Therapeutics, Inc.)	Adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy	Gene Therapy Product	19-Dec-2017	Still in market	Click Here for Link to FDA Website
YESCARTA (axicabtagene ciloleucel) (Kite Pharma, Incorporated)	A CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma	Gene Therapy Product	18-Oct-2017	Still in market	Click Here for Link to FDA Website
KYMRIAH (tisagenlecleucel) (Novartis Pharmaceuticals Corporation)	CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse	Gene Therapy Product	30-Aug-2017	Still in market	Click Here for Link to FDA Website

MACI (Vericel Corporation)	Autologous Cultured Chondrocytes on a Porcine Collagen Membrane for the repair of single or multiple symptomatic, full-thickness cartilage defects of the knee with or without bone involvement in adults	Tissue Engineered Product	13-Dec-2016	Still in market	Click Here for Link to FDA Website
Clevecord (HPC, Cord Blood) (Cleveland Cord Blood Center)	For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment	Cell Therapy Product	1-Sep-2016	Still in market	Click Here for Link to FDA Website
HPC, Cord Blood (Bloodworks)	For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment	Cell Therapy Product	28-Jan-2016	Still in market	Click Here for Link to FDA Website
IMLYGIC (talimogene laherparepvec) (Amgen Inc.)	Genetically modified oncolytic viral therapy indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery	Gene Therapy Product	27-Oct-2015	Still in market	Click Here for Link to FDA Website
HPC, Cord Blood (LifeSouth Community Blood Centers, Inc.)	For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment	Cell Therapy Product	13-Jun-2013	Still in market	Click Here for Link to FDA Website

ALLOCORD (SSM Cardinal Glennon Children's Medical Center)	For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment	Cell Therapy Product	30-May-2013	Still in market	Click Here for Link to FDA Website
Ducord (HPC, Cord Blood) (Duke University School of Medicine)	For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment	Cell Therapy Product	4-Oct-2012	Still in market	Click Here for Link to FDA Website
HPC, Cord Blood (Clinimmune Labs, University of Colorado Cord Blood Bank)	For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment	Cell Therapy Product	24-May-2012	Still in market	Click Here for Link to FDA Website
GINTUIT (Organogenesis, Inc.)	Allogeneic Cultured Keratinocytes and Fibroblasts in Bovine Collagen (cellular sheets) for topical (non-submerged) application to a surgically created vascular wound bed in the treatment of mucogingival conditions in adults	Tissue Engineered Product	9-Mar-2012	Still in market	Click Here for Link to FDA Website
Hemacord (HPC, Cord Blood) (New York Blood Center, Inc.)	For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment	Cell Therapy Product	1-Nov-2011	Still in market	Click Here for Link to FDA Website

Laviv® (Azficel-T) (Fibrocell Technologies, Inc.)	Autologous fibroblasts for improvement of the appearance of moderate to severe nasolabial fold wrinkles in adults	Cell Therapy Product	21-Jun-2011	Still in market	Click Here for Link to FDA Website
PROVENGE (sipuleucel-T) (Dendreon Corporation)	Autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer	Cell Therapy Product	29-Apr-2010	Still in market	Click Here for Link to FDA Website

List of Cell/Tissue/Gene Products with Regenerative Medicine Advanced Therapy (RMAT) Designation [4] in the United States by US-FDA (United States Food and Drug Administration, August 2018)

Name (MA Holder)	Product description and indication(s)	Product category	Date of RMAT Designation	Additional designations	Additional information
SB623 (SanBio Group)	Modified and cultured adult bone marrow-derived mesenchymal stem cells that undergo temporary genetic modification for the treatment of chronic neurological motor deficits secondary to traumatic brain injury (TBI)	Gene Therapy Product	19-Sep-2019		Press Release
MGTA-456 (Magenta Therapeutics)	Cell therapy for the treatment of multiple inherited metabolic disorders	Cell Therapy Product	4-Sep-2019		Press Release
MB-107 (Mustang Bio)	Lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency (known as “bubble boy disease”)	Gene Therapy Product	22-Aug-2019		Press Release
OTL-103 (Orchard Therapeutics)	Ex vivo autologous hematopoietic stem cell (HSC)-based gene therapy for the treatment of Wiskott-Aldrich Syndrome (WAS)	Gene Therapy Product	29-July-2019		Press Release
SB-525 (Sangamo Therapeutics, Inc. and Pfizer, Inc.)	A recombinant adeno-associated virus serotype 6 vector (AAV6) encoding the complementary deoxyribonucleic acid for B domain deleted human FVIII for the treatment of severe hemophilia A	Gene Therapy Product	05-July-2019	Orphan Drug; Fast Track	Press Release
KB103 (Krystal Biotech, Inc.)	Replication-defective, non-integrating viral vector that has been engineered to deliver functional human COL7A1 genes directly to the patients’ skin cells for treatment of dystrophic epidermolysis bullosa (DEB)	Gene therapy product	24-June-2019		Press Release

Viralym-M (ALVR105) (AlloVir)	Allogeneic, off-the-shelf, multi-virus specific T-cell therapy, for the treatment of hemorrhagic cystitis (HC) caused by BK virus in adults and children following allogeneic hematopoietic stem cell transplantation (HSCT)	Cell Therapy Product	11-June-2019		Press Release
FCX-007 (Fibrocell Science, Inc.)	Genetically-modified autologous fibroblasts for the treatment of RDEB, a congenital and progressive orphan skin disease caused by the deficiency of the protein COL7	Gene Therapy Product	29-May-2019	Orphan Drug; Rare Pediatric Disease; Fast Track	Press Release
ECT-001 (ExCellThera)	Hematologic malignancies	Cell Therapy Product	23-Apr-2019		Press Release
FCR001 (Talaris Therapeutics)	Allogeneic cell therapy to induce or restore living donor kidney transplant (LDKT) recipient immune tolerance	Cell Therapy Product	18-Apr-2019	Orphan Drug	Press Release
RP-L102 (Rocket Pharmaceuticals, Inc.)	Lentiviral vector (LVV)-based gene therapy for the treatment of Fanconi Anemia (FA)	Gene therapy product	27-Nov-2018	Fast Track	Press Release
lifileucel (Iovance Biotherapeutics, Inc.)	Adoptive cell therapy using tumor-infiltrating lymphocytes (TIL) for metastatic melanoma	Cell Therapy Product	06-Nov-2018		Press Release
P-BCMA-101 (Poseida Therapeutics Inc.)	Autologous CAR-T therapy targeting cells that express B cell maturation antigen, or BCMA, to treat patients with relapsed/refractory multiple myeloma	Gene Therapy Product	5-Nov-2018		Press Release
Avance® Nerve Graft (AxoGen, Inc.)	Off-the-shelf processed human nerve allograft intended for the surgical repair of peripheral nerve discontinuities.	Cell Therapy Product	29-Oct-2018		Press Release
AT132 (Audentes Therapeutics, Inc.)	AAV-mediated gene therapy for the treatment of X-linked Myotubular Myopathy (XLMTM), a rare monogenic disease caused by mutations in the MTM1 gene	Gene Therapy Product	21-Aug-2018	Rare Pediatric Disease; Fast Track; Orphan Drug	Press Release
Romylocel-L (Cellerant Therapeutics, Inc.)	Off-the-shelf human myeloid progenitor cells for the prevention of serious bacterial and fungal infections in patients with de novo acute myeloid leukemia (AML) undergoing induction chemotherapy	Cell Therapy Product	02-Jul-2018		Press Release
VY-AADC (Voyager Therapeutics, Inc.)	AAV-mediated gene therapy for the treatment of Parkinson's disease in patients with motor fluctuations that are refractory to medical management	Gene Therapy Product	21-Jun-2018		Press Release

CLBS14-RfA (Caladrius Biosciences, Inc.)	CD34+ cell therapy program for the treatment of refractory angina	Cell Therapy Product	19-Jun-2018		Press Release
NSR-REP1 (Nightstar Therapeutics plc)	AAV-mediated gene therapy for the treatment of choroideremia, a rare, degenerative, genetic retinal disorder that leads to blindness	Gene Therapy Product	14-Jun-2018		Press Release
VM202 (ViroMed Co.)	DNA-based drug designed to produce two isoforms of HGF (hepatocyte growth factor) for the treatment of painful diabetic peripheral neuropathy	Gene Therapy Product	May 2018		Press Release
ABO-102 (Abeona Therapeutics Inc.)	AAV-mediated gene therapy for the treatment of Sanfilippo syndrome Type A (MPS IIIA), a rare autosomal-recessive lysosomal storage disease	Gene Therapy Product	23-Apr-2018		Press Release
AmnioFix® (MiMedx)	Allogeneic micronized dehydrated human amnion/chorion membrane for use in the treatment of Osteoarthritis (OA) of the knee	Tissue Engineered Product	9-Mar-2018		Press Release
CAP-1002 (Capricor Therapeutics)	Allogeneic cell therapy (cardiosphere-derived cells) that is currently in clinical development for the treatment of Duchenne muscular dystrophy	Cell Therapy Product	5-Feb-2018	Orphan Drug; Rare Pediatric Disease	Press Release
EB-101 (Abeona Therapeutics Inc.)	Gene-corrected autologous cell therapy product for patients with recessive dystrophic epidermolysis bullosa (RDEB)	Gene Therapy Product	29-Jan-2018	Breakthrough therapy; Orphan Drug; Rare Pediatric Disease	Press Release
Revascor (MPC-150-IM) (Mesoblast Limited)	Mesenchymal precursor cell (MPC) therapy in the treatment of heart failure patients with left ventricular systolic dysfunction and left ventricular assist devices (LVADs)	Cell Therapy Product	21-Dec-2017		Press Release
MPC therapy (Mesoblast Limited)	Mesenchymal precursor cell (MPC) therapy in the treatment of heart failure patients with left ventricular systolic dysfunction and left ventricular assist devices (LVADs)	Cell Therapy Product	21-Dec-2017		Press Release
CEVA101 (Cellvation)	Autologous bone marrow-derived stem cells for the treatment of traumatic brain injury	Cell Therapy Product	8-Nov-2017		Press Release
Multistem (Athersys)	Proprietary stem cell product for the treatment of ischemic stroke	Cell Therapy Product	5-Oct-2017		Press Release

AST-OPC1 (Asterias Biotherapeutics)	Oligodendrocyte progenitor cells manufactured from pluripotent embryonic stem cell for treatment of spinal cord injury patients	Cell Therapy Product	2-Oct-2017	Press Release
LentiGlobin® BB305 (Bluebird Bio)	Ex-vivo modified autologous hematopoietic stem cells for treatment of transfusion-dependent β -thalassemia (also known as β -thalassemia major) and severe sickle cell disease (SCD)	Gene Therapy Product	1-Oct-2017	Press Release
ATIR101™ (Kiadis Pharma)	Adjunctive immunotherapeutic on top of allogeneic hematopoietic stem cell transplantation (HSCT)	Cell Therapy Product	20-Sep-2017	Press Release
StrataGraft (Mallinckrodt plc)	Autologous skin cell product for the treatment of deep partial thickness burns	Tissue Engineered Product	18-Jul-2017	Press Release
Ixmyelocel-T (Vericel)	Autologous expanded multicellular (mesenchymal cells, monocytes and alternatively activated macrophages) product for the treatment of patients with advanced heart failure due to ischemic dilated cardiomyopathy	Cell Therapy Product	10-May-2017	Press Release
jCell (jCyte)	Adult retinal progenitor cells for the treatment of retinitis pigmentosa (RP)	Cell Therapy Product	2-May-2017	Press Release
RVT-802 (Enzyvant)	Allogeneic thymic tissue for the treatment of primary immune deficiency resulting from complete diGeorge Syndrome (cDGS)	Cell Therapy Product	17-Apr-2017	Breakthrough Therapy, Rare Pediatric Disease, Orphan Drug Press Release
HUMACYL® (Humacyte)	Human acellular vessel (HAV) for patients undergoing hemodialysis	Tissue Engineered Product	20-Mar-2017	Press Release
JCAR017 (Juno Therapeutics)	Treatment of r/r aggressive large B-cell Non-Hodgkin Lymphoma	Gene Therapy Product		