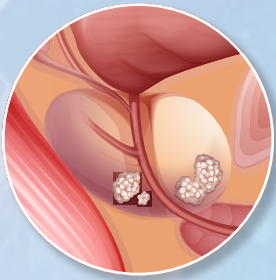


Approved Cell Therapy Products

It is undisputed that the cell therapy market, projected to be **valued at over \$62 billion by 2030**, will expand considerably in the next five to ten years. Whether it will grow as much as ResearchandMarkets predicts is anyone's guess but based on the increasing number of clinical trials for cell-based therapies, it is definitely a burgeoning market with tremendous potential benefits to patients and companies.

Over **20 cellular therapy products** have been approved so far* by the U.S. FDA's Office of Tissues and Advanced Therapies. Provenge, the first approved cellular therapy, got the green light from the U.S. FDA more than 13 years ago. Unfortunately, it was ahead of its time, and poor sales resulted in bankruptcy and several changes of ownership. Some of the subsequent approvals have not fared much better and are no longer widely available. However, many of the more recent approvals, like Yescarta and Tecartus, have been much more successful, racking up impressive sales, likely fueling even more interest in the field.

This infographic lists the cell therapies approved in the last 13 years by the U.S. FDA, including the HPC (hematopoietic progenitor cell) Cord Blood products for patients with hematopoietic system disorders that are inherited, acquired, or due to myeloablative treatment, which are summarized at the end.



Provenge

A therapeutic cancer vaccine, Dendreon's Provenge (sipuleucel-T) was approved in 2010 for the treatment of asymptomatic or minimally symptomatic metastatic prostate cancer.



Laviv

Approved in 2011 as the first personalized aesthetic cell therapy, Laviv (Azcifcel-T) is indicated for improvement of the appearance of moderate to severe nasolabial fold wrinkles. This autologous cell therapy was developed by Fibrocell Science.



Gintuit

Approved in 2012, Organogenesis' Gintuit (Allogeneic Cultured Keratinocytes and Fibroblasts in Bovine Collagen) is indicated for the treatment of mucogingival conditions in adults.



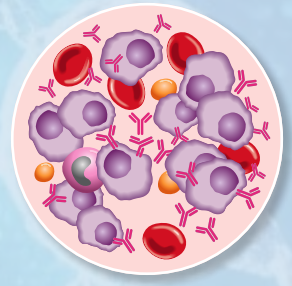
Imlygic

From Amgen, Imlygic (talimogene laherparepvec) is for the treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery. The genetically modified oncolytic viral therapy was approved in October 2015.



MACI

Vericel's MACI (Autologous Cultured Chondrocytes on a Porcine Collagen Membrane) was approved in 2016. It is used for the repair of cartilage damage of the knee.

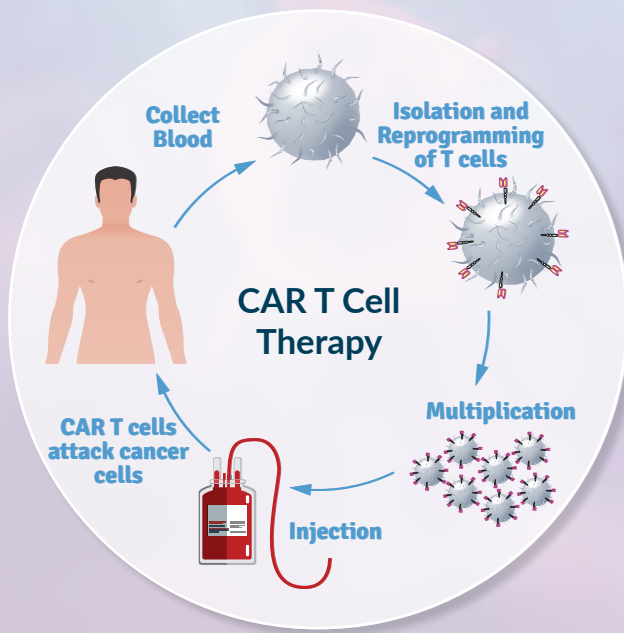


Abecma

A one-time infusion for adult patients with R/R multiple myeloma, Abecma (idecabtagene vicleucel) was approved in March 2021. This autologous cell therapy is manufactured by Cellegene, a Bristol-Myers Squibb Company.

Kymriah

Kymriah (tisagenlecleucel), was the first CAR T cell therapy approved by the U.S. FDA (in August 2017). It is indicated for the treatment of children and young adults with relapsed or refractory acute lymphoblastic leukemia. The one-time treatment from Novartis was subsequently approved for the treatment of adult patients with R/R diffuse large B-cell lymphoma (May 2018) as well as R/R follicular lymphoma (May 2022).



Tecartus

Tecartus (brexucabtagene autoleucel), for treatment of R/R mantle cell lymphoma, was approved in July 2020. The autologous, anti-CD19 CAR T cell therapy is manufactured by Kite, a Gilead Company, and was approved for adult acute lymphoblastic leukemia in October 2021.

Breyanzi

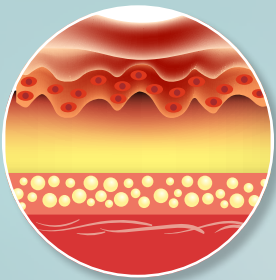
Breyanzi (lisocabtagene maraleucel) is a CAR T cell therapy used to treat large B cell lymphoma. Juno Therapeutics received approval for this autologous cell therapy in February 2021.

Yescarta

Another autologous CAR T cell therapy from Kite Pharma, Yescarta (axicabtagene ciloleucel) was approved in March 2021 for R/R follicular lymphoma and in April of 2022 for the treatment of adult patients with R/R large B-cell lymphoma.

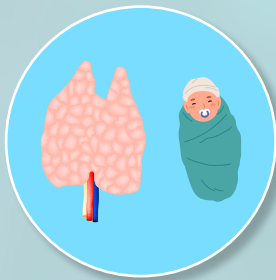
Carvykti

Manufactured by Janssen Biotech, Carvykti (ciltacabtagene autoleucel), a CAR T cell therapy, received approval in February 2022 for the treatment of adults with R/R multiple myeloma.



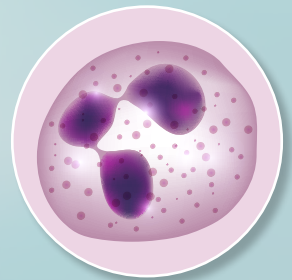
Stratagraft

Stratagraft (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen-dsat) was approved in June 2021 for the treatment of deep partial-thickness burns (DPT). This skin graft alternative is manufactured by Mallinckrodt's Stratetech.



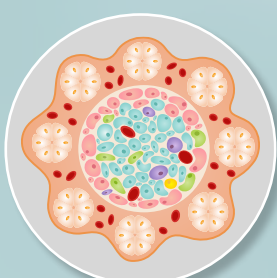
Rethymic

Sumitovant Biopharma's subsidiary Enzyvant Therapeutics won approval for Rethymic (allogeneic processed thymus tissue-agdc) in October 2021. The one-time regenerative tissuebased therapy is used in pediatric patients with congenital athymia (a condition where infants are born without a thymus).



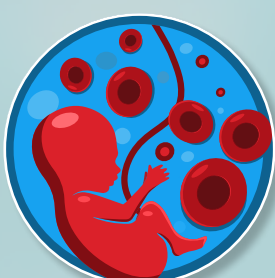
Omisirge

Gamida Cell's allogeneic cell therapy Omisirge® (omidubicel-only) was approved in April 2023 for use in adult and pediatric blood cancer patients following radiation or chemotherapy. It is intended to reduce the risk of infection by speeding the recovery of neutrophils.



Lantidra

CellTrans' Lantidra (donislecel), is a cell therapy that helps to restore functional pancreatic islet cells in patients unable to produce insulin. Approved in June 2023, it is the first cell therapy to be okayed by the FDA for adults with type 1 diabetes.



Approved HPC, Cord Blood products

Allocord, Clevecord, Ducord, Hemacord, and HPC, Cord Blood from **University of Colorado Cord Blood Bank**, from **MD Anderson Cord Blood Bank**, **LifeSouth Community Blood Centers**, and **BloodWorks**.

*As of June 30, 2023