

First FDA-Approved Cell Therapy for Leukemia Utilizes Thermo Fisher Scientific's CTS Dynabeads Technology

Kymriah™ (tisagenlecleucel, formerly CTL019), the first FDA-approved CAR-T cell therapy, uses CTS Dynabeads CD3/CD28 spherical beads to isolate, activate and expand T cells

WALTHAM, Mass., Aug. 30, 2017 /[PRNewswire](#)/ -- The U.S. Food and Drug Administration (FDA) has approved a new cell therapy 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. The Novartis chimeric antigen receptor T cell (CAR-T) cell therapy, Kymriah™ (tisagenlecleucel, formerly CTL019), is the first FDA-approved CAR-T immunotherapy, and uses specifically developed Cell Therapy Systems ([CTS™](#)) [Dynabeads™](#) technology, part of Thermo Fisher's Cell Therapy Systems (CTS) portfolio. The magnetic beads isolate, activate and expand T cells that have been genetically engineered to recognize and fight cancer cells in each individual patient. Thermo Fisher's longstanding partnership with Novartis is an example of its commitment to accelerate precision medicine.

The company's collaboration with Novartis was originally announced on July 31, 2013 and has since evolved from exclusive to non-exclusive providing the opportunity for other CAR-T cell therapy developers to adopt Thermo Fisher's "*ready for commercial drug manufacturing*" T cell isolation, activation and expansion platform.

Thermo Fisher's proprietary magnetic bead platform is already enabling research, development and commercial manufacturing of other cancer-treating CAR-T cell therapies globally. In cell therapy manufacturing, CTS Dynabeads CD3/CD28 beads deliver a scalable platform that streamlines production while ensuring high reproducibility.

"Kymriah is an example of the rigor required to deliver viable cell therapies to physicians and their patients," said Alan Sachs, chief scientific officer at Thermo Fisher Scientific. "We established a dedicated facility and a validated aseptic manufacturing process to ensure that our technology met the strict quality standards set by Novartis."

The process for manufacturing Kymriah requires removing blood cells from the patient, isolating and reprogramming the T cells to recognize and attack cancer cells before infusing them back into the patient. CAR-T treatment embodies precision medicine because each patient's therapy is manufactured expressly for them using their own cells.

Dynabeads products are for research use only or for the manufacturing of cell-, gene- or tissue-based products.

Kymriah is a trademark of Novartis.

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