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Trial aims to extend remission for children treated with T-cell immunotherapy for leukemia

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After phase 1 results of Seattle Children's Pediatric Leukemia Adoptive Therapy (PLAT-02) trial have shown T-cell immunotherapy to be effective in getting 93 percent of patients with relapsed or refractory acute lymphoblastic leukemia (ALL) into complete initial remission, researchers have now opened a first-in-human clinical trial aimed at reducing the rate of relapse after the therapy, which is about 50 percent. The new phase 1 pilot study, PLAT-03, will examine the feasibility and safety of administering a second T-cell product intended to increase the long-term persistence of the patient's chimeric antigen receptor (CAR) T cells that were reprogrammed to detect and destroy cancer.

The research team, led by Dr. Mike Jensen at the Ben Towne Center for Childhood Cancer Research at Seattle Children's Research Institute, is exploring this strategy after discovering that of the patients who relapse in the PLAT-02 trial, about half of them have lost their CAR T cells. Lasting persistence of the CAR T cells is critical in combating a recurrence of cancer cells.

"While it's promising that we're able to get these patients who are very sick back into remission, we're also seeing that the loss of the CAR T cells in some patients may be opening the door for the cancer to return," said Dr. Colleen Annesley, an oncologist at Seattle Children's and the lead investigator of the PLAT-03 trial. "We're pleased to now be able to offer patients who have lost or are at risk of losing their cancer-fighting

T cells an option that will hopefully lead to them achieving long-term remission."

In the PLAT-03 trial, patients will receive "booster" infusions of a second T-cell product, called T antigen-presenting cells (T-APCs). The T-APCs have been genetically modified to express the CD19 target for the cancer-fighting CAR T cells to recognize. Patients will receive a full dose of T-APCs every 28 days for at least one and up to six doses. By stimulating the CAR T cells with a steady stream of target cells to attack, researchers hope the CAR T cells will re-activate, helping to ensure their persistence long enough to put patients into long-term remission.

PLAT-03 is now open to patients who first enroll in phase 2 of Seattle Children's PLAT-02 trial and who are also identified as being at risk for early loss of their reprogrammed CAR T cells, or those who lose their reprogrammed CAR T cells within six months of receiving them.

The PLAT-03 trial is one of several trials that Seattle Children's researchers are planning to open within the next year aimed at further improving the long-term efficacy of T-cell immunotherapy. In addition to the current T-cell immunotherapy trial that is open for children with neuroblastoma, researchers also hope to expand this promising therapy to other solid tumor cancers.

"We are pleased to be at a pivotal point where we are now looking at several new strategies to further improve CAR T-cell immunotherapy so it remains a long-term defense for all of our patients," said Dr. Rebecca Gardner, Seattle Children's oncologist and the lead investigator of the PLAT-02 trial. "We're also excited to be working to apply this therapy to several other forms of pediatric cancer beyond ALL, with the hope that T-cell immunotherapy becomes a first line of defense, reducing the need for toxic therapies and minimizing the length of treatment to only weeks."

To read about the experience of one of the patients in the PLAT-02 trial, please visit Seattle Children's On the Pulse blog.

Provided by Seattle Children's Research Institute

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