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that 88 percent achieved complete remissions after being treated with genetically modified versions of their own immune cells. The results were published today in *Science Translational Medicine*.

“These extraordinary results demonstrate that cell therapy is a powerful treatment for patients who have exhausted all conventional therapies,” said [Michel Sadelain, MD, PhD](#), Director of the [Center for Cell Engineering](#) at Memorial Sloan Kettering and one of the study’s senior authors. “Our initial findings have held up in a larger cohort of patients, and we are already looking at new clinical studies to advance this novel therapeutic approach in fighting cancer.”

Adult B cell acute lymphoblastic leukemia (B-ALL), a type of blood cancer that develops in B cells, is difficult to treat because the majority of patients relapse. Patients with relapsed B-ALL have few treatment options; only 30 percent respond to salvage chemotherapy. Without a successful bone marrow transplant, few have any hope of long-term survival.

In the current study, 16 patients with relapsed B-ALL were given an infusion of their own genetically modified immune cells, called T cells. The cells were “reeducated” to recognize and destroy cancer cells that contain the protein CD19. While the overall complete response rate for all patients was 88 percent, even those with detectable disease prior to treatment had a complete response rate of 78 percent, far exceeding the complete response rate of salvage chemotherapy alone.

Dennis J. Billy, C.Ss.R, of Wynnewood, Pennsylvania, was one of the first patients to receive this treatment more than two years ago. He was able to successfully undergo a bone marrow transplant and has been cancer-free and back at work teaching theology since 2011. Paolo Cavalli, a restaurant owner from Oxford, Connecticut, remains in complete remission eight months after receiving his personalized T cell treatment.

## A History of Scientific Achievements for Cell-Based Therapies

Cell-based, targeted immunotherapy is a new approach to treating cancer that harnesses the body’s own immune system to attack and kill cancerous cells. Unlike with a common virus such as the flu, our immune system does not recognize cancer cells as

foreign and is therefore at a disadvantage in eradicating the disease. For more than a decade, researchers at Memorial Sloan Kettering have been exploring ways to reengineer the body's own T cells to recognize and attack cancer. In 2003, they were the first to report that T cells engineered to recognize the protein CD19, which is found on B cells, could be used to treat B cell cancers in mice.

"Memorial Sloan Kettering was the first center to report successful outcomes using this CD19-targeted approach in B-ALL patients," said Renier Brentjens, MD, PhD, Director of Cellular Therapeutics at Memorial Sloan Kettering and one of the study's senior authors. "It's extremely gratifying to witness the astonishing results firsthand in my patients, having worked for more than a decade developing this technology from the ground up."

In March 2013, the same team of researchers first reported the results of five patients with advanced B-ALL who were treated with cell therapy. Remarkably, all five patients achieved complete remissions.

#### Results Demonstrate Potential of New Therapy

In the current study, seven of the 16 patients (44 percent) were able to successfully undergo bone marrow transplantation — the standard of care and the only curative option for B-ALL patients — following treatment. Three patients were ineligible due to failure to achieve a complete remission, three were ineligible due to preexisting medical conditions, two declined, and one is still being evaluated for a potential bone marrow transplant. Historically, only 5 percent of patients with relapsed B-ALL have been able to transition to bone marrow transplantation.

The study also provides guidelines for managing side effects of cell therapy, which can include severe flu-like symptoms such as fever, muscle pain, low blood pressure, and difficulty breathing, referred to as cytokine release syndrome. The researchers developed diagnostic criteria and a laboratory test that can identify which patients are at greater risk for developing this syndrome.

Additional studies to determine whether cell therapy can be applied to other types of cancer are already underway, and studies to test whether B-ALL patients would benefit from receiving targeted immunotherapy as frontline treatment are being planned.

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