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UPDATE 1-Novartis CAR-T therapy leads to durable response in lymphoma study



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Dec 10 (Reuters) - Patients with an advanced form of an aggressive blood cancer who had initially responded to Novartis' new type of gene-modifying immunotherapy continued to respond at least six months after treatment, according to updated data released at a medical meeting on Sunday.

Among 46 patients with at least six months of follow-up after treatment with Novartis' Kymriah for diffuse large B-cell lymphoma (DLBCL), 30 percent still had a complete response, meaning no detectable sign of cancer, with another 7 percent achieving a partial response.

The results indicate that, in the 81-patient study, those with no sign of cancer after three months remained relapse-free at six months and beyond, researchers reported at the American Society of Hematology meeting in Atlanta.

"Patients that are in complete remission by 3 to 6 months are going to have durable remissions," said Dr. Stephen Schuster, the trial's lead investigator, who has patients from an earlier pilot study alive more than three years after Kymriah treatment.

Kymriah belongs to a new class of therapy called CAR-T. It works by harvesting a patient's own disease-fighting T-cells, genetically engineering them to target specific proteins on cancer cells, and replacing them to circulate possibly for years, seeking out and attacking cancer.

"The technology is spectacular," said Schuster, from the University of Pennsylvania's Abramson Cancer Center. "We're able to save the lives of people that just a few years ago we couldn't. I can't express the amount of satisfaction and excitement that I have."

The one-time treatment with a list price of \$475,000 was approved in August for patients up to 25 years of age with advanced acute lymphoblastic leukemia (ALL), becoming the first CAR-T treatment to market. A second from Gilead Sciences was later approved.

Novartis has applied for U.S. and European approval for Kymriah to treat adults with DLBCL, a common, aggressive type of non-Hodgkin lymphoma.

Patients in the study had relapsed or failed to respond to multiple rounds of chemotherapy plus stem cell transplants for about half of them, exhausting virtually all available options. They were allowed to receive additional chemotherapy while awaiting return of their engineered cells, an average turnaround time of about three weeks.

The cells can also be frozen until a patient is deemed clinically ready to receive them.

At the latest interim analysis, median duration of response had not been reached, meaning more than half the patients who responded had not experienced disease return or progression.

There were no deaths attributed to cytokine release syndrome or neurological side effects, both potentially dangerous reactions to the treatment.

Novartis expects to have 35 centers capable of processing Kymriah fully operational by the end of the year.

"We are in an amazing time," Schuster said, "and it's really just the beginning."

(Reporting by Bill Berkrot; Editing by Nick Zieminski and Peter Cooney)

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