

**The Times of India**

**Title : US panel endorses new gene-altering cancer treatment**

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A US Food and Drug Administration panel opened a new era in medicine on Wednesday, unanimously recommending that the agency approve the first-ever treatment that genetically alters a patient's own cells to fight cancer, transforming them into what scientists call "a living drug" that powerfully bolsters the immune system to shut down the disease.

If the Food and Drug Administration accepts the recommendation, which is likely, the treatment will be the first gene therapy to reach the market. Others are expected: Researchers and drug companies have been in intense competition for decades to reach this milestone. Novartis is poised to be the first with a treatment for a type of leukemia. The pharma giant is working on similar types of treatments for another form of the disease, as well as multiple myeloma and an aggressive brain tumor.

To use the technique, a separate treatment must be created for each patient -their cells removed at an approved medical centre, frozen, shipped to a Novartis plant for thawing and processing, frozen again and shipped back to the treatment centre.

A single dose of the resulting product has brought long remissions, and possibly cures, to scores of patients in studies who were facing death because every other treatment had failed. The panel recommended approving the treatment for B-cell acute lymphoblastic leukemia that has resisted treatment, or relapsed, in children and young adults aged three to 25.

One of those patients, Emily Whitehead, now 12 and the first child ever given the altered cells, was at the meeting to advocate for approval of the drug. In 2012, as a six-year-old, she was treated in a study at the Children's Hospital of Philadelphia. Severe side effects -raging fever, crashing blood pressure, lung congestion -nearly killed her. But she emerged cancer free, and has remained so.

"We believe that when this treatment is approved it will save thousands of children's lives," Emily's father, Tom Whitehead, told the panel.

The main evidence that Novartis presented to the FDA came from a study of 63 patients who received the treatment from April 2015 to August 2016. Fifty-two of them, or 82.5%, went into remission -a high rate for such a severe disease. Eleven others died.

**THE CURE WITHIN**

➤ In gene therapy, the patient is genetically altered to enable his/her **own cells to fight cancer**

➤ Each treatment is unique. Patient's cells are sent to a centre for **gene-alteration**

➤ Single dose of resultant product has helped scores of **patients beat back leukemia** in studies