FDA Approves Talvey and Elrexfio for Heavily Pretreated Multiple Myeloma

The Leukemia & Lymphoma Society funded research leading to a type of targeted immunotherapy called bispecific antibodies.

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The U.S. Food and Drug Administration (FDA) in August approved both talquetamab-tgvs (Talvey) and elranatamab (Elrexfio) to treat adults with multiple myeloma that has failed to respond or has relapsed despite previous treatments.

Talquetamab and elranatamab are a form of targeted immunotherapy called bispecific antibodies and are the first ever in this class approved to treat multiple myeloma. Four other bispecific antibodies were previously approved to treat other forms of blood cancer.

Immunotherapy works by helping a patient's own immune system attack their cancer. While some immunotherapies work by engaging with one target, usually immune system T cells, as their name implies bispecific antibodies work in two ways simultaneously.

Talquetamab binds to a protein known as GPCR5D, that is highly expressed on the surface of multiple myeloma cells. The other part of the drug binds to an immune cell called a T-cell. Once the T-cell binds to the myeloma cell, it can kill the myeloma cell without harming other cells.

Elranatamab does the same thing except elranatamab binds to BCMA, a different protein target that is unique to myeloma cells.

Both drugs were evaluated in patients who received at least four different therapies for their multiple myeloma. More than 70% of the 100 patients treated with talquetamab in the clinical trial had a positive response to the treatment and for 85% of them, the response lasted at least nine months. In a similar number of patients, 58% of those treated with elranatamab derived a response to treatment with a lasting response observed in the majority nearly a year later (11.1 months).

"LLS provided funding for groundbreaking research that helped identify proteins on the surface of myeloma cells and would be appropriate targets for immunotherapy," said LLS's chief scientific officer Lee Greenberger, PhD. "This research paved the way to bring much-needed therapeutic options for patients with multiple myeloma who oftentimes have a poor prognosis."

LLS has long recognized the importance of immunotherapy during its more than 70-year history. In the 1970s, LLS funded work to learn how the immune system can eradicate leukemia after a bone marrow transplant (where the immune cells come from a donor).

Stepping Up When No One Else Would

In the 1990s, LLS was among the first to invest in what has become chimeric antigen receptor T-cell therapy (CAR T)—when even the National Institutes of Health (NIH) declined to fund the work. LLS's sustained investment, now more than $100 million, has translated into 12 CAR T-cell therapy approvals to treat blood cancers of all types.

The success of CAR T has paved the way for a flurry of development in new therapies to treat blood cancer. While CAR T was groundbreaking, one substantial challenge in its use is that it needs to be tailored for each individual patient, a process that can take many weeks to complete; time that some patients don't have. Bispecific antibodies are "off the shelf" treatments that bypass this problem.

"The first bispecific antibody was approved to treat blood cancer in 2014, and now there have been five more in the past nine months," says Dr. Greenberger. "It is very clear that immunotherapy extends patients' lives and improves quality of life compared to older one-size-fits all, toxic chemotherapy regimens."

LLS Continues to Lead the Way

But Dr. Greenberger notes that with new technology and an investment in a deeper understanding of the immune system, there is much more to do, and LLS is again leading the way.

"Immunotherapy has proven that it can be used to cure some patients of blood cancers," says Dr. Greenberger. "However, we need to realize the full potential of this approach. That is why 28%, or $57 million, of LLS's world-wide current funds, which includes academic grants and venture philanthropy used to fund emerging biotech companies, is directed to improving immunotherapy. Understanding how the immune system works, or in some cases fails to work, can be used not only to cure blood cancers, but also possibly prevent blood cancers in the future."

If you or a loved one need personalized disease, treatment or support information, you can contact one of the LLS Information Specialists: https://www.lls.org/support-resources/information-specialists.

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