

FDA OKs Two Novel Immunotherapies for Cancer

Amtagvi is the first approved tumor-infiltrating lymphocyte therapy and Anktiva is the first interleukin 15 agonist.

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The Food and Drug Administration recently approved two new types of cancer immunotherapy.

lovance's Amtagvi (lifileucel), the first tumor-infiltrating lymphocyte (TIL) therapy, was granted accelerated approval for advanced melanoma after nearly 40 years of research on T-cell therapies for solid tumors. While many T cells are unable to get inside tumors, TILs have proven cancer-fighting ability. T cells are collected from a patient's tumor, multiplied in a lab and infused back into the body.

In a Phase II analysis of 73 patients with previously treated inoperable or metastatic melanoma, the overall response rate was 32%, including three people (4%) with complete responses. Among the responders, 44% were still alive without disease progression at 12 months.

"This approval is transformative for the entire research field and supports continued investigation of TIL cell therapy across additional types of solid tumors," says TIL pioneer Steven Rosenberg, MD, of the National Cancer Institute.

ImmunityBio's Anktiva (nogapendekin alfa inbakicept), the first interleukin 15 agonist, was approved for people with non-muscle invasive bladder cancer. The treatment activates both T cells and natural killer cells to attack tumors. What's more, it stimulates the production of memory T cells, leading to a long-lasting response.

In a Phase II/III trial of 77 patients, the complete response rate was 62%. Among those with a complete response, 58% had a duration of response lasting at least one year, and 40% did so for at least two years.

Days after the bladder cancer approval, ImmunityBio announced top-line results from another Phase II trial showing that Anktiva plus a checkpoint inhibitor nearly doubled overall survival for people with non-small-cell lung cancer. The treatment is also being explored for several other types of cancer and even for HIV.

“This novel mechanism of action, which mimics the biology of the dendritic cell, begins the evolution of immunotherapy beyond T cells alone,” says ImmunityBio executive chairman Patrick Soon-Shiong, MD.

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