# FDA Approves New Type of Immunotherapy for Early Bladder Cancer

Anktiva, an IL-15 agonist, also shows promise for other malignancies, including non-small-cell lung cancer, and even for HIV.

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On April 22, the Food and Drug Administration (FDA) approved Anktiva (nogapendekin alfa inbakicept), a novel type of immunotherapy that promotes the activity of natural killer cells and T cells, for people with non-muscle invasive bladder cancer. The new treatment is expected to be available in the United States by mid-May.

Noninvasive bladder cancer, meaning early-stage cancer that has not yet penetrated the organ's outer muscular wall, typically involves surgery to remove tumors and intravesical therapy, or medications inserted into the bladder through a catheter. The standard intravesical immunotherapy is Bacillus Calmette-Guérin (BCG), weakened bacteria related to those that cause tuberculosis. Introducing BCG into the bladder stimulates an immune response that destroys cancer cells, but it doesn't work for everyone, and those who initially respond often experience recurrence, which can lead to more radical surgery to remove the entire bladder.

Anktiva (formerly known as N-803), from the biotechnology company ImmunityBio, is a first-in-class interleukin 15 receptor agonist that activates natural killer (NK) cells and killer T cells to attack tumors. What's more, the treatment stimulates the production of memory T cells, leading to a long duration of response.

"Anktiva not only proliferates and activates the patient's own NK cells and CD8+ killer T cells, but also activates CD4+ T helper cells, thus enhancing the proliferation of memory killer T cells," celebrity entrepreneur Patrick Soon-Shiong, MD, ImmunityBio's executive chairman and global chief scientific and medical officer, said in a news release. "This novel mechanism of action, which mimics the biology of the dendritic cell, begins the evolution of immunotherapy beyond T cells alone."

The new FDA indication is for adults with BCG-unresponsive non-muscle invasive bladder cancer with carcinoma in situ, with or without papillary tumors. Around 80% of bladder cancer patients

have non-muscle invasive cancer at the time of diagnosis.

The safety and efficacy of Anktiva were evaluated in the Phase II/III QUILT-3.032 trial (NCT0302285), which enrolled 77 people with this type of bladder cancer after surgical resection. They initially received Anktiva plus BCG as induction therapy, followed by maintenance therapy for up to 37 months.

The complete response rate, meaning no remaining cancer, was 62%. Among patients with a complete response, 58% had a duration of response lasting at least one year and 40% responded for at least two years. Some patients' responses have exceeded 47 months and counting, and the median duration of response has not yet been reached, according to the news release. The FDA previously declined approval of Anktiva in May 2023 pending this longer duration of response data. More detailed results will be presented next week at the American Urological Association annual meeting.

"The long duration of complete response ranging over 47 months is a game changer for non-muscle invasive bladder cancer patients and provides further clinical evidence of Anktiva's effectiveness for patients who historically have faced high rates of recurrence and significantly diminished quality of life due to radical surgeries," said principal investigator Karim Chamie, MD, of the University of California Los Angeles.

Treatment was safe and generally well tolerated, and most side effects were mild to moderate. The most common adverse reactions include pain or burning on urination, frequent urination, urinary urgency, blood in the urine, urinary tract infections, muscle and joint pain, chills and fever. The most common lab abnormalities were increased creatinine and increased potassium.

The recommended Anktiva dose is 400 micrograms administered intravesically with BCG once weekly for six weeks as induction therapy. A second induction course may be given if a complete response is not achieved by three months. For maintenance therapy, the recommended dose is 400 mcg of Anktiva plus BCG once weekly for three weeks at months 4, 7, 10, 13 and 19, for a total of 15 doses. For patients with an ongoing complete response at two years, nine additional maintenance doses of Anktiva and BCG may be administered. Treatment should be discontinued if a patient experiences disease persistence after the second induction course, recurrence or progression, or unacceptable side effects.

## Beyond Bladder Cancer

Anktiva has been studied in multiple Phase I and II trials that have included more than 700 people with blood cancers or solid tumors. Given its mechanism of action, Anktiva may be a good partner for immune checkpoint inhibitors, which unleash T-cell activity. What's more, its long duration of response could approach that of a vaccine.

"The FDA's approval of Anktiva marks our launch of a next-generation immunotherapy beyond checkpoint inhibitors," said Soon-Shiong. "The 'triangle offense' of tumor cell killing by the body's immune system with long-term memory is the foundation of our efforts to develop a therapeutic

cancer vaccine across multiple tumor types, regardless of the site of origin."

Days after the bladder cancer approval, ImmunityBio announced topline results from the Phase II QUILT-3.055 trial (NCT03228667), which showed that Anktiva in combination with a checkpoint inhibitor—Keytruda (pembrolizumab), Opdivo (nivolumab) or Tecentriq (atezolizumab)—improved overall survival for non-small-cell lung cancer patients who did not respond or progressed despite receiving the same checkpoint inhibitor with or without chemotherapy. The news release said that median overall survival was "almost double," but did not provide detailed data. ImmunityBio plans to meet with the FDA in June to discuss approval of Anktiva for lung cancer.

"The results we noted with the completion of the QUILT 3.055 basket trial across multiple tumor types in patients with late-stage cancers for whom standard of care plus checkpoints failed, validates our hypothesis that orchestration of NK cells with killer T cells and memory T cells could result in meaningful clinical improvements to current standards of care," Soon-Shiong said in the second news release. "We hypothesized that activation and proliferation of natural killer cells through IL-15 stimulation could rescue T cells after checkpoint failure, regardless of tumor type or of tumor location."

Anktiva is also being evaluated for colorectal cancer, non-Hodgkin lymphoma and glioblastoma, and future studies are planned for ovarian cancer and acute myeloid leukemia, according to the company. Researchers are also exploring whether this new type of immunotherapy might play a role in curing HIV.

Click here for full prescribing information for Anktiva.

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