FDA approves immunotherapy drug combo for non-muscle invasive bladder cancer

April 23 2024

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The U.S. Food and Drug Administration (FDA) has approved the immunotherapy-boosting drug N-803, which is marketed under the brand name Anktiva, to be used in combination with the immunotherapy

Bacillus Calmette-Guerin (BCG) for the treatment of patients with BCG-unresponsive non–muscle-invasive bladder cancer.

The decision was based on results of the QUILT 3.032 clinical trial, which was led by Dr. Karim Chamie, associate professor of urology at the David Geffen School of Medicine at UCLA and a researcher at the UCLA Health Jonsson Comprehensive Cancer Center.

Findings from the phase 2/3 trial were presented at the 2022 American Society of Clinical Oncology annual meeting and published in *NEJM Evidence*. Chamie, who was the principal investigator for the trial, reported that this combination treatment resulted in longer overall survival and was more effective and safer than other treatments available for BCG-unresponsive non–muscle-invasive bladder cancer.

"The FDA approval of N-803 heralds a new era in the management of BCG-unresponsive non–muscle-invasive bladder cancer," said Chamie. "By leveraging the body's immune system to mount a targeted attack against cancer cells, N-803 offers a compelling alternative for patients who have exhausted conventional treatment options. What makes this really remarkable is its ability to spare patients from invasive procedures, like a cystectomy, significantly enhancing the quality of life for patients."

Roughly 80% of new bladder cancer diagnoses are non-muscle invasive bladder cancer, which is found in the tissue that lines the inner surface of the bladder and hasn't spread into the bladder wall. Patients with this type of cancer usually undergo surgery to remove the tumor, followed by treatment with a bacteria-based immunotherapy called BCG, which is placed directly into the bladder. The treatment triggers an inflammatory response in the bladder that helps prevent cancer recurrence.

However, even with this treatment, the cancer can come back, and many

patients don't respond well to further BCG treatment, leaving limited treatment options. For some patients, they may require surgery to remove the bladder entirely, facing significant risks like bleeding, kidney issues, and infections, especially for older patients.

The QUILT 3.032 study evaluated the addition of the investigational drug N-803 to the treatment regimen to see if it can help boost the effectiveness of BCG.

Developed by ImmunityBio, N-803 is a protein that helps activate the body's immune cells to fight cancer by promoting the proliferation and activation of natural killer cells and $CD8^+$ T cells, which are crucial components of the body's immune response against cancer cells.

Investigators enrolled 171 patients (81% male with a median age of 72) with non–muscle-invasive bladder cancer who didn't respond well to BCG treatment from clinical locations across the country. The UCLA Health team enrolled 28 patients, making UCLA the top enrolling center.

The participants were then divided into two cohorts: one with carcinoma in situ and the other with papillary disease.

For the carcinoma in situ cohort, 71% of patients had a complete response ranging over 47 months, meaning they no longer had evidence of the disease or had any symptoms of the cancer. The response lasted for a median duration of 26.6 months. At 24 months, a cystectomy and surgical removal of the bladder were avoided in over 90% of patients. All of the participants in the study (100%) were still alive after a two-year follow-up.

For the papillary cohort, 57% remained disease-free after 12 months and 48% after 24 months. Additionally, 94% of the patients in this group also avoided cystectomy.

"The treatment was particularly effective for carcinoma in situ patients, with a high complete response rate and long-lasting response," Chamie said. "Even for papillary disease, the treatment showed good results in keeping the cancer from coming back and avoiding the need for cystectomy. Overall, the treatment was safer and more effective than other options available for BCG-unresponsive non–muscle-invasive bladder cancer."

Provided by University of California, Los Angeles

Citation: FDA approves immunotherapy drug combo for non-muscle invasive bladder cancer (2024, April 23) retrieved 25 June 2024 from https://medicalxpress.com/news/2024-04-fda-immunotherapy-drug-combo-muscle.html

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