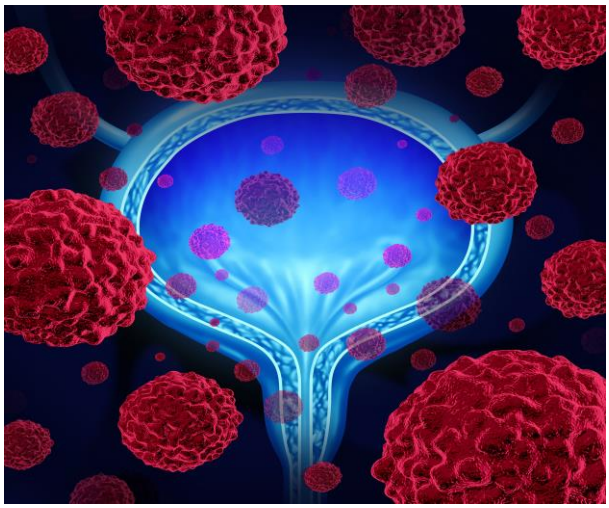
FDA Approves Anktiva Plus Bacillus Calmette-Guérin For Non-Muscle Invasive Bladder Cancer

The approval was based on the QUILT-3.032 study, which included 77 adults with carcinoma in situ with or without papillary tumors after a transurethral resection.

The FDA has approved nogapendekin alfa inbakicept-pmln (Anktiva, N-803; ImmunityBio Inc) plus Bacillus Calmette-Guérin (BCG) for patients with BCG-unresponsive non-muscle invasive bladder cancer with carcinoma *in situ*, with or without papillary tumors, according to a press release.[1]

According to a study in *Investigative and Clinical Urology*, approximately 75% to 80% of bladder cancers are non-muscle invasive bladder cancer, with intravesical BCG being recommended for those with intermediate or high-risk disease. The unresponsive rate with BCF ranged from 30% to 50%, and authors said that enhanced alternative treatments are needed to address this patient population. Currently intravesical valrubicin, adstiladrin, and systemic pembrolizumab are approved by the FDA for this patient population.[2]



Nogapendekin alfa inbakicept-pmln is an interleukin-15 receptor for intravesical use only, according to the prescribing information. In the induction period, 400 mcg is administered with BCG once a week for 6 weeks, with a second induction course if a complete response is not achieved at 3 months. For maintenance, 400 mcg is administered with BCG once a week for 3 weeks at 4 months, 7 months, 10 months, 13 months, and 19 months. If patients have an ongoing complete response (CR) at 25 months and later, additional maintenance doses with BCG may be administered once a week for 3 weeks at 25 months, 31 months, and 37 months.[3]

The approval was based on the QUILT-3.032 study, which was a single-arm, multicenter trial that included 77 adults with BCG-unresponsive non-muscle invasive bladder cancer with carcinoma with or without papillary tumors after a transurethral resection, the prescribing information showed. Patients received 400 mcg of the study drug for 6 consecutive weeks during the induction period at the previously mentioned timeframes, and for those with high grade or persistent disease at 3 months, patients received a second induction course. Those who had an ongoing CR continued treatment at 25 months, 31 months, and 37 months.[3]

Investigators assessed tumor states every 3 months for up to 2 years, with assessments for ongoing response beyond 24 months being based on local community standards. Random, or cystoscopy directed, biopsies were required within 6 months post-treatment initiation. The efficacy outcomes were CR at any time and duration of response (DOR).[3]

Between July 2017 and January 2022, individuals were enrolled in the trial, with a median age of 73 years; 87% were male and 90% were white, according to the study authors. Study results were published in the *New England Journal of Medicine*, showing there were approximately 62% of individuals who achieved a complete response, with 58% having a duration of over 12 months and 40% having a duration of over 24 months, according to the prescribing information.[3,4]

Safety was also evaluated in the study, including cohort A, made up of 88 individuals in the patient population who were dosed the same as in the efficacy cohort. Serious adverse reactions occurred in 16%, including hematuria. There was 1 patient who received the drug and BCG that experienced a fatal reaction of cardiac arrest. Permanent discontinuation occurred in 7% of individuals, with musculoskeletal pain accounting for 2.3%.[3,4]

The most common adverse reactions, including laboratory test abnormalities, included increased creatine, dysuria, hematuria, urinary frequency, micturition urgency, urinary tract infection, increased potassium, musculoskeletal pain, chills, and pyrexia.[3] Further, the prescribing information indicates that the drug could cause fetal harm, so it should not be used for pregnant individuals.[3]

References

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2. Jeong SH, Ku JH. Treatment strategies for the Bacillus Calmette-Guérin-unresponsive non-muscle invasive bladder cancer. *Investig Clin Urol*. 2023;64(2):103-106. doi:10.4111/icu.20230042
3. ImmunityBio. Anktiva (nogapendekin alfa inbakicept-pmln) solution [package insert]. US Food and Drug Administration website. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761336s000lbl.pdf. April 2024. Accessed April 23, 2024.
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About The QUILT-3.032

Trial Name: A Multicenter Clinical Trial of Intravesical Bacillus Calmette-Guerin (BCG) in Combination With ALT-803 (N-803) in Patients With BCG Unresponsive High Grade Non-Muscle Invasive Bladder Cancer

ClinicalTrials.gov ID: NCT03022825

Sponsor: ImmunityBio Inc

Completion Date (Estimated): October 2028

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