



THE EFFICACY AND TOLERABILITY TO KEEP FIGHTING.



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Anktiva is the only IL-15 receptor agonist that re-engages the immune system in patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors.

Study design: QUILT-3.032 is a multicenter, single-arm study in adults with BCG-unresponsive high-risk NMIBC with CIS ± Ta/T1 papillary disease. Efficacy was evaluated in 77 adults (label), with updated follow-up in 100 patients. Patients received nogapendekin alfa inbakicept-pmln 400 mcg plus BCG weekly for 6 weeks, with re-induction permitted at month 3. The primary endpoint was complete response.^{1,2}

Complete response ability.

Biopsy confirmed complete response in the majority of patients.

FDA Label Population



Primary Endpoint

of study participants achieved a complete response, meaning their cancer was eliminated (n=77; 95% CI: 51-73).¹

Biopsy confirmed.

Full Enrollment Follow-up



Primary Endpoint

of study participants achieved a complete response (n=100; 95% CI: 61.1-79.6).²

Biopsy confirmed.

Durable response.

FDA Label Population



Duration of Response

58% (n=28) of patients with duration ≥12 months; 40% (n=19) of patients with duration ≥24 months; range: 0.0–47.0+ months.¹

+ Denotes an ongoing response.

Full Enrollment Follow-up



Duration of Response

Some patients remained NMIBC-free for over 4 years.²

+ Denotes an ongoing response.

BCG, Bacillus Calmette-Guérin; CIS, carcinoma in situ; NMIBC, nonmuscle invasive bladder cancer.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE: ANKTIVA is an interleukin-15 (IL-15) receptor agonist indicated with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

WARNINGS AND PRECAUTIONS: Risk of Metastatic Bladder Cancer with Delayed Cystectomy. Delaying cystectomy can lead to the development of muscle invasive or metastatic bladder cancer, which can be lethal. If patients with CIS do not have a complete response to treatment after a second induction course of ANKTIVA with BCG, reconsider cystectomy.

Please see additional Important Safety Information on next page.

Safety results from the QUILT-3.032 study.

Adverse events occurring in ≥15% of patients in Cohort A in the QUILT-3.032 Study¹

Adverse Reaction	Anktiva with BCG ¹ (n=88)	
	All Grades, %	Grades 3 or 4, %
Dysuria	32	0
Hematuria ^a	32	3.4
Urinary Frequency	27	0
Micturition Urgency ^a	25	0
Urinary Tract Infection ^a	24	2.3
Musculoskeletal Pain ^a	17	2.3
Chills	15	0
Pyrexia	15	0

a. Includes other related terms.

Clinically relevant adverse reactions in <15% of patients who received Anktiva with BCG included fatigue (14%), nausea (14%), bladder irritation (11%), diarrhea (9%), and nocturia (7%).

Select laboratory test abnormalities (≥15%) that worsened from baseline in patients in Cohort A in the QUILT-3.032 Study¹

Laboratory Abnormality	Anktiva with BCG ¹ (n=88)	
	All Grades, %	Grades 3 or 4, %
Increased Creatinine ^a	76	0
Increased Potassium ^a	18	2

a. The denominator used to calculate the rates was 88 based on the number of patients with a baseline value and at least one post-treatment value.

Discontinuation due to adverse events occurred in 7% of patients in the QUILT-3.032 study.

INDICATION AND IMPORTANT SAFETY INFORMATION (Cont'd)

DOSAGE AND ADMINISTRATION: For Intravesical Use Only. Do not administer by subcutaneous or intravenous routes. Instill intravesically only after dilution. Total time from vial puncture to the completion of the intravesical instillation should not exceed 2 hours.

USE IN SPECIFIC POPULATIONS: Pregnancy: May cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS: The most common (≥15%) adverse reactions, including laboratory test abnormalities, are increased creatinine, dysuria, hematuria, urinary frequency, micturition urgency, urinary tract infection, increased potassium, musculoskeletal pain, chills and pyrexia.

For more information about ANKTIVA, please see the full Prescribing Information at www.anktiva.com.

You are encouraged to report negative side effects of prescription drugs to FDA. Visit www.FDA.gov/medwatch or call 1-800-332-1088. You may also contact ImmunityBio at 1-877-ANKTIVA (1-877-265-8482)

References: 1. Anktiva (nogapendekin alfa inbakicept-pmln) prescribing information. ImmunityBio, 2024. 2. Chang S. (2025, April 26-29). An Update on QUILT-3.032: Durable Complete Responses to NAI (ANKTIVA) Plus BCG Therapy in BCG-Unresponsive CIS With or Without Ta/T1 Papillary Disease and in Papillary Disease without CIS. [Conference Presentation]. AUA2025, Las Vegas, Nevada, United States.

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