Anktiva®
(nogapendekin alfa inbakicept-pmln)
400 mcg/0.4 mL, solution for intravesical instillation

Visit ANKTIVA.com to learn more or scan the QR code.

THE EFFICACY AND TOLERABILITY TO KEEP FIGHTING.

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.[1]

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 (FDA label), with full enrollment follow-up in 100 patients. Patients received ANKTIVA 400 mcg plus BCG weekly for 6 weeks, with re-induction permitted at month 3. The primary endpoint was complete response at any time, defined as negative cystoscopy (with TURBT/biopsies as applicable) and urine cytology.[1,2]

COMPLETE RESPONSE ABILITY.

Confirmed by bladder biopsies at Months 3 and 6.*

FDA Label Population[1]

Primary Endpoint

of study participants achieved a complete response (n=77; 95% CI: 51-73).

Full Enrollment Follow-up[2]

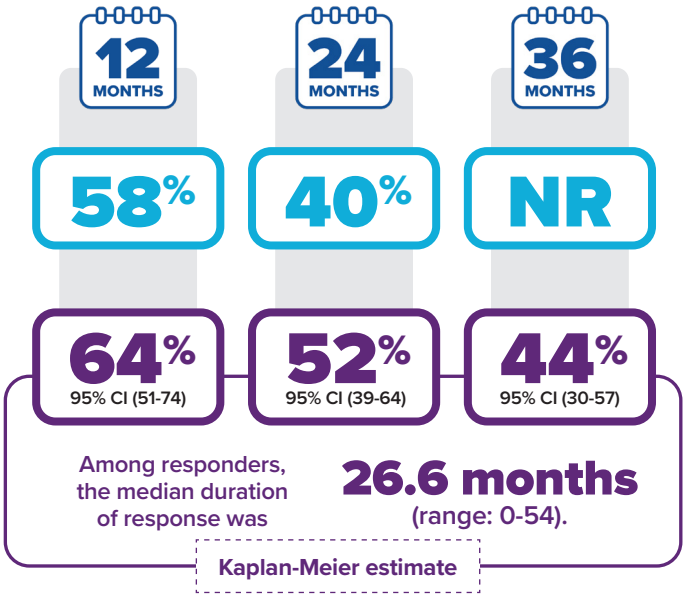
Primary Endpoint

of study participants achieved a complete response (n=100; 95% CI: 61-80).

*Biopsy confirmation provides tissue-level evidence that no cancer was detected at the time of assessment.[1,2]

A DURABLE RESPONSE.

Patients who achieved a complete response were followed over time to assess how long the response lasted.



BCG, Bacillus Calmette-Guérin; CIS, carcinoma in situ; IL, interleukin; NMIBC, nonmuscle invasive bladder cancer; NR, not yet reached.

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.

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ANKTIVA + BCG HAS BEEN SHOWN TO BE

WELL TOLERATED.

Safety results from the QUILT-3.032 study.

Adverse Reactions Occurring in ≥15% of Patients in Cohort A in the FDA Label Population[1]

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

*Includes other related items.

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%).[1]

Adverse Reactions Occurring in ≥15% of Patients in Cohort A in the Full Enrollment Follow-up[2]

Adverse Reactions	ANKTIVA with BCG (n=100)	
	All Grades 1-2, %	Grades 3 or 4, %
Dysuria	26	0
Pollakiuria	23	0
Hematuria	19	1

Clinically relevant adverse reactions (all grades) in <15% of patients who received ANKTIVA with BCG included micturition urgency (14%), fatigue (12%), urinary tract infection (8%), and bladder spasm (7%).[2]

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/PI.

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, et al. *J Urol*. 2026; Accepted for publication; in press.

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