Anktiva®
(nogapendekin alfa inbakicept-pmln)

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The Power of ANKTIVA®

To Generate IL-15 Activated NK, Killer T, and Memory T Cells with No Immunosuppressive T Reg Cells

The efficacy outcome measures for the QUILT-3.032 study were complete response (CR) at any time, defined as negative cystoscopy and urine cytology, and duration of response.

In the pivotal trial, ANKTIVA® + BCG delivered robust and durable complete responses.[1]

71% CR

of study participants had a complete response, meaning their cancer was eliminated
(n=100) (95% CI=61.1,79.6)
Biopsy confirmed

Duration of Response

53+ Months

Meaning some study participants remained NMIBC-free for over 4 years
+ Denotes an ongoing response

% of Responders Who Were Cystectomy Free at 36 Months

84%

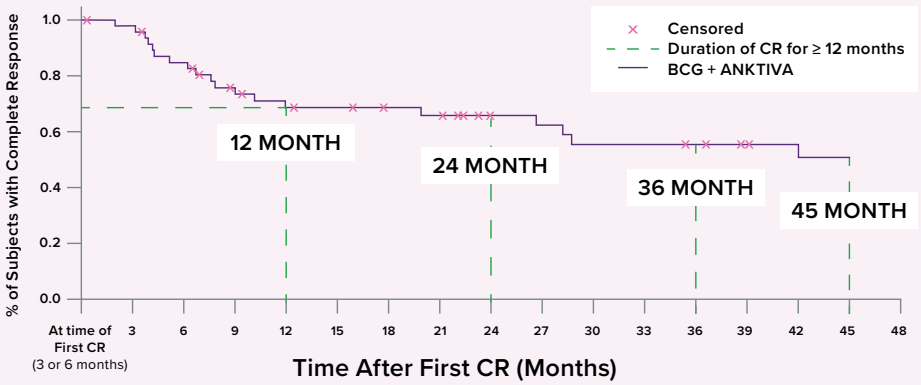
Disease-Specific Overall Survival at 36 Months

99%

Proven Durability

The following dataset reflects an updated follow up of the 77 patients in the ANKTIVA prescribing information demonstrating the durability of response of ANKTIVA plus BCG.[1]

Kaplan Meier (KM) Duration of Complete Response (n=77)



Duration of response showing probability of duration 12, 24, 36, and 45 months.

KM Duration of Complete Response

- **69%** 12 MONTH DOR 95% CI (53/80)
- **66%** 24 MONTH DOR 95% CI (50/78)
- **59%** 36 MONTH DOR 95% CI (38/70)
- **51%** 45 MONTH DOR 95% CI (33/66)

The tables below are from the ANKTIVA package insert.

TABLE 1: Adverse Reactions Occurring in ≥15% of Patients in Cohort A IN QUILT-3.032

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

1. 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%).

TABLE 2: Select Laboratory Test Abnormalities (≥15%) that Worsened from Baseline in Patients in Cohort A of QUILT-3.032

Laboratory Abnormality	ANKTIVA with BCG[1] (n=88)	
	All Grades %	Grades 3 or 4 %
Increased Creatinine	76	0
Increased Potassium	18	2

1. 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.

1. 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.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE: ANKTIVA is an interleukin-15 (IL-15) receptor agonist indicated with ß 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. **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).