Anktiva®
(nogapendekin alfa inbakicept-pmln)

The Power of IL-15 Receptor Alpha

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 delivered robust and durable complete responses[1,2]

62%[1] CR

(n=77) (95% CI=51,73)
(FDA Efficacy Population)

Prolonged Duration of Response

Range of Duration of Response[1]

0.0 to 47+ Months

and Ongoing
Represents the Upper Limit of the Range of Duration

In the following data, published in the peer-reviewed journal *NEJM Evidence*, all participants that met the QUILT 3.032 study protocol criteria are included. This is a broader set of participants than included in the product data sheet, to which the FDA applied additional criteria.

% of Responders Who Were Cysectomy Free at 24 Months[2]

89.2%

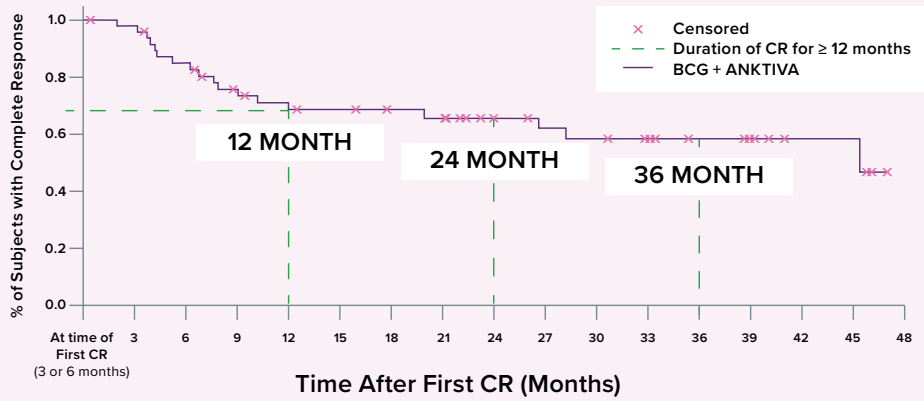
(Data from QUILT 3.032 study investigators as published in *NEJM Evidence*)

Overall Survival of all Study Participants at 24 Months[2]

94%

(Data from QUILT 3.032 study investigators as published in *NEJM Evidence*)

Kaplan Meier (KM) Duration of Complete Response (n=77)[3]



Duration of response showing probability of duration 12, 24 and 36 months.[1,3]

KM Duration of Complete Response[3]

12 MONTH DOR
69%
95% CI (53/80)

24 MONTH DOR
66%
95% CI (50/78)

36 MONTH DOR
59%
95% CI (41/72)

1. ANKTIVA Package insert. ImmunityBio, Inc.; 2024.
2. Chamie K, et al. IL-15 Superagonist NAI in BCG-Unresponsive Non-Muscle-Invasive Bladder Cancer. NEJM Evid. 2023 Jan;2(1): EVIDoa2200167. doi: 10.1056/EVIDoa2200167.
3. P. Soon-Shiong, Oral Presentation (MP16-03) AUA May 2024 Presentation.

Open your camera and point your smart device at the QR code to access Anktiva.com

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.

TABLE 3: Efficacy Results in QUILT-3.032

	ANKTIVA with BCG[1] (n=77)
Complete Response Rate (95% CI)	**62% (51, 73)**
Duration of Response[a]	
Range in months	0.0, 47.0+
% (n) with duration ≥ 12 months	58% (28)
% (n) with duration ≥ 24 months	40% (19)

\+ Denotes ongoing response

a. Based on 48 patients that achieved a complete response at any time; reflects period from the time complete response was achieved

The aforementioned tables are from the ANKTIVA package insert.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE: ANKTIVA is an interleukin-15 (IL-15) receptor agonist indicated with Bacillus Calmette-Guerin (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).

Anktiva®
(nogapendekin alfa inbakicept-pmln)

For more information about ANKTIVA, please see the Full Prescribing Information at ANKTIVA.com