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Anktiva is indicated with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-unresponsive nonmuscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

The unique **mechanism of action (MOA)** of Anktiva activates the body's natural immune system by proliferating natural killer cells, killer T cells, and memory T cells to drive durable T cell memory and durable responses.

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.

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}



Duration of Response

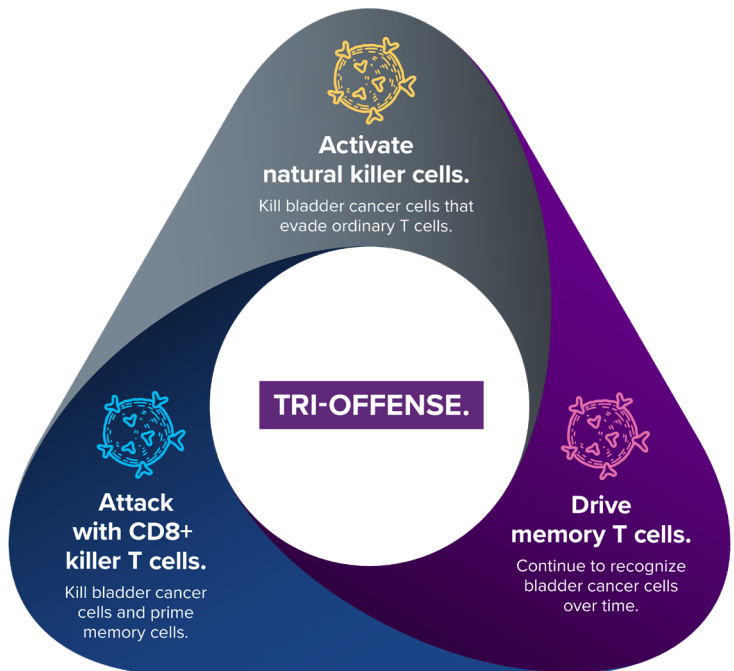
58% (n=28) of patients with duration ≥12 months; 40% (n=19) of patients with duration ≥24 months; range: 0.0–47.0+ months.¹
 + Denotes an ongoing response.

Full Enrollment Follow-up



Primary Endpoint

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



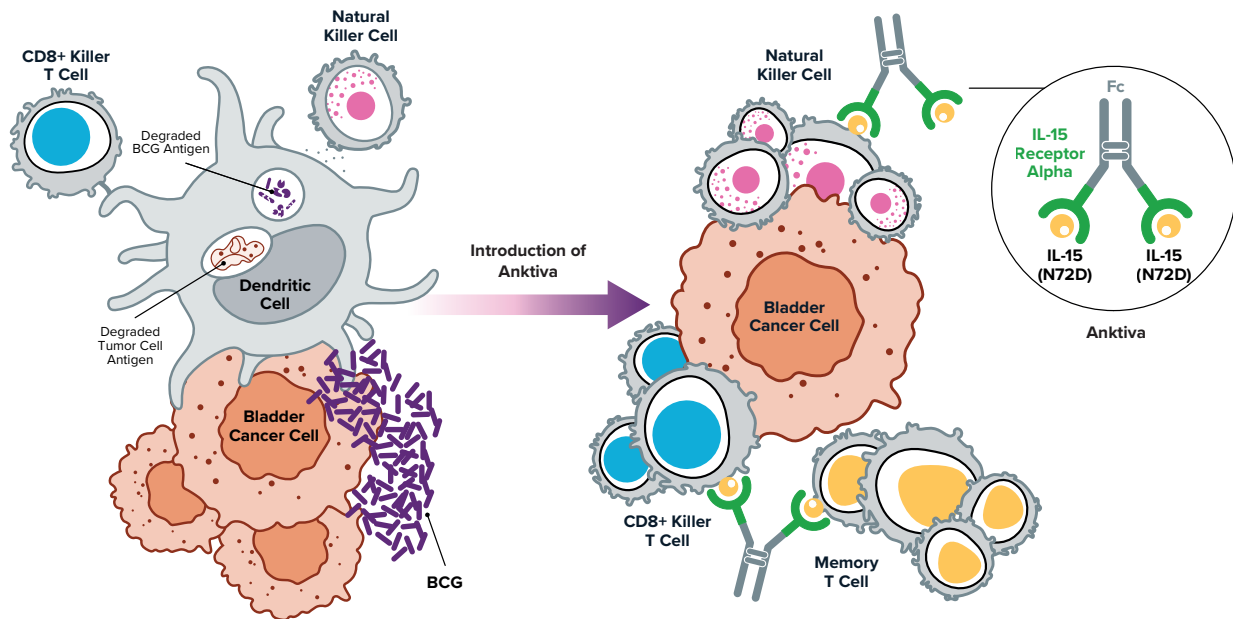
Duration of Response

Some patients remained NMIBC-free for over 4 years.²
 + Denotes an ongoing response.

Activating the innate and adaptive immune system without activation of immunosuppressive T Regs

Anktiva MOA Harnessing Nature's Immune System

Anktiva synergizes with BCG, activating innate (NK) and adaptive (T cell) immune memory^{2,3}



BCG works by triggering an immune response through antigen-presenting cells like dendritic cells. However, not all patients respond to BCG alone. When that happens, Anktiva can help by activating both the innate and adaptive immune systems.

Anktiva is a novel immunotherapy that harnesses the body's natural defenses to target and attack BCG-unresponsive NMIBC CIS. This approach offers the potential for a more durable response.

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.

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 ($\geq 15\%$) 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 ibakicept-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. **3.** Han KP, et al. IL-15:IL-15 receptor alpha superagonist complex: high-level co-expression in recombinant mammalian cells, purification and characterization. *Cytokine*. 2011 Dec; 56(3):804-10. doi: 10.1016/j.cyto.2011.09.028.