

11 December 2025
EMADOC-1829012207-35903
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Anktiva

nogapendekin alfa inbakicept

On 11 December 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional² marketing authorisation for the medicinal product Anktiva. The applicant for this medicinal product is ImmunityBio Ireland Limited.

The full indication is:

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

Anktiva will be available as 400 µg concentrate for intravesical suspension. The active substance of Anktiva is nogapendekin alfa inbakicept, an interleukin (ATC code: L03AC03). Anktiva is an interleukin-15 (IL-15) receptor agonist that enhances immune responses by stimulating CD4+ and CD8+ T cells, as well as NK cells.

The benefits of Anktiva are a 71% (95% CI: 61.1, 79.6) complete response rate and 26.6 months (95% CI: 13.0, 49.9) median duration of complete response in adults with BCG-unresponsive NMIBC with CIS, with or without papillary tumours, in a single-arm, open-label, phase 2/3 study. The most common side effects with Anktiva are dysuria, haematuria, pollakiuria, urinary tract infection, micturition urgency, fatigue, chills, musculoskeletal pain and pyrexia.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is expected to provide comprehensive clinical data at a later stage.