Anktiva® (nogapendekin alfa inbakicept-pmln) – New drug approval

- On April 22, 2024, ImmunityBio announced the FDA approval of Anktiva (nogapendekin alfa inbakicept-pmln), in combination 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.

- The standard therapy for NMIBC is intravesical instillation of BCG. BCG is a benign bacteria that induces an immune response in the bladder in proximity to the cancer cells, leading to clearance of the cancer in many patients.

    — The American Cancer Society estimates there will be 83,190 new cases and 16,840 deaths from bladder cancer in 2024. At the time of diagnosis, about 80% of cases are NMIBC.

- Anktiva is a first-in-class interleukin-15 (IL-15) agonist immunotherapy. IL-15 plays a role in the immune system by affecting the development, maintenance, and function of key immune cells that are involved in killing cancer cells.

- The efficacy of Anktiva was established in QUILT-3.032, a single-arm study in 77 adults with BCG-unresponsive, high-risk, NMIBC with CIS with or without Ta/T1 papillary disease following transurethral resection. The major efficacy measures were complete response (CR) at any time and duration of response (DOR).

    — The CR was 62% (95% CI: 51, 73).
    — The DOR range was 0.0 to 47.0+ months.

- A warning and precaution for Anktiva is risk of metastatic bladder cancer with delayed cystectomy.

- The most common adverse reactions (≥ 15%), including laboratory test abnormalities, with Anktiva use were increased creatinine, dysuria, hematuria, urinary frequency, micturition urgency, urinary tract infection, increased potassium, musculoskeletal pain, chills and pyrexia.

- The recommended intravesical induction dose of Anktiva is 400 mcg administered intravesically with BCG once a week for 6 weeks. A second induction course may be administered if complete response is not achieved at month 3.

    — For maintenance: After BCG and Anktiva induction therapy, Anktiva is recommended at a dose of 400 mcg administered intravesically with BCG once a week for 3 weeks at months 4, 7, 10, 13 and 19 (for a total of 15 doses). For patients with an ongoing complete response at month 25 and later, maintenance instillations with BCG may be administered once a week for 3 weeks at months 25, 31, and 37 for a maximum of 9 additional instillations.
    — The recommended duration of treatment is until disease persistence after second induction, disease recurrence or progression, unacceptable toxicity, or a maximum of 37 months.

- ImmunityBio plans to launch Anktiva in mid-May 2024. Anktiva will be available as a 400 mcg/0.4 mL single-dose vial.