DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Charles Garlisi, PhD
Senior Vice President, Regulatory Affairs
Altor BioScience, LLC, (an indirect wholly-owned subsidiary of ImmunityBio, Inc.)
25 DeForest Avenue, Suite 201
Summit, NJ 07901

RE: BLA 761336
ANKTIVA® (nogapendekin alfa inbakicept-pmln) solution, for intravesical use
MA 35

Dear Dr. Garlisi:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, the "Efficacy and Safety" webpage[1] (webpage) on the ANKTIVA Healthcare Provider Branded Website (ANK-00079-US-v4.0)[2] for ANKTIVA® (nogapendekin alfa inbakicept-pmln) solution, for intravesical use (Anktiva) submitted by Altor BioScience LLC, an indirect wholly-owned subsidiary of ImmunityBio, Inc. (Altor) under cover of Form FDA 2253. The FDA Bad Ad Program also received a complaint regarding promotional communications with representations similar to those discussed in this letter. FDA has determined that the webpage is false or misleading. Thus, the webpage misbrands Anktiva and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The "Efficacy and Safety" webpage includes the following efficacy representations regarding cystectomy avoidance and disease-specific survival (DSS) (in pertinent part, emphasis original, footnotes omitted):

- "**% of Responders Who Were Cystectomy Free At 36 Months**
  - **84%**"

- "**Disease-Specific Overall Survival at 36 Months**
  - **99%**"

These representations on the webpage misbrand Anktiva by misleadingly suggesting that QUILT-3.032 provided interpretable results regarding the effects of Anktiva on cystectomy avoidance and DSS, even though the design of the QUILT-3.032 study was not capable of establishing improvement on these time-to-event efficacy endpoints. Anktiva was approved based on an effect shown on complete response and duration of response in QUILT-3.032, a

[1] The "Efficacy & Safety" webpage is accessed from the "Efficacy & Safety" sub-navigation menu of the website. See: https://anktiva.com/hcp/efficacy-safety. (last accessed September 4, 2025).
[2] The material ID referenced on the "Efficacy & Safety" webpage is "ANK-00079-US v11."

single-arm study. As a reference for these representations, you cite a presentation[3] by Chang S, which includes updated results from the QUILT-3.032 study. However, as QUILT-3.032 was designed as a single-arm study (i.e., with no comparator arm) and cystectomy avoidance and DSS are time-to-event efficacy endpoints, the reported cystectomy avoidance and DSS results are uninterpretable; absent an appropriate comparator, it is not possible to determine if the observed effect is attributable to Anktiva or to other factor(s), such as the natural history of the disease.

Conclusion and Requested Action

For the reasons described above, the webpage misbrands Anktiva and makes the distribution of the drug in violation of the FD&C Act.

This letter notifies you of our concerns and provides you with an opportunity to address them. FDA requests that Altor take immediate action to address any violations (including, for example, ceasing and desisting promotional communications that are misleading as described above). Please submit a written response to this letter within 15 working days from the date of receipt, addressing the concerns described in this letter, listing all promotional communications (with the 2253 submission date) for Anktiva that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Anktiva.

If you believe that your product is not in violation of the FD&C Act, please include in your submission to us your reasoning and any supporting information for our consideration within 15 working days from the date of receipt of this letter.

The concerns discussed in this letter do not necessarily constitute an exhaustive list of potential violations. It is your responsibility to ensure compliance with each applicable requirement of the FD&C Act and FDA implementing regulations.

Please direct your response to the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Ammendale Road, Beltsville, Maryland 20705-1266**. A courtesy copy can be sent by facsimile to (301) 847-8444. Please refer to MA 35 in addition to the BLA number in all future correspondence relating to this particular matter. All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter. You are encouraged, but not required, to submit your response in eCTD format. All correspondence submitted in response to this letter should be placed under eCTD Heading 1.15.1.6. Additionally, the response submission should be coded as an Amendment to eCTD Sequence 0192 under BLA 761336.

[3] Chang S. 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. Presentation at: AUA2025; April 26-29, 2025; Las Vegas, NV.

Questions related to the submission of your response letter should be emailed to CDER-OPDP-RPM@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

George Tidmarsh, M.D., Ph.D.
Director
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CARTER M BEACH
09/09/2025 05:16:21 PM
On behalf of George Tidmarsh, M.D., Ph.D