DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Nick Senior, PharmD, JD
Director Regulatory Affairs, Oncology DRA A&P
Novartis Pharmaceuticals Corporation
One Health Plaza, Bldg 337
East Hanover, NJ 07936-1080

RE: NDA 215833
PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) injection, for intravenous use
MA 587

Dear Dr. Senior:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer (DTC) broadcast advertisement (FA-11446517) (TV ad) for PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) injection, for intravenous use (Pluvicto) submitted by Novartis Pharmaceuticals Corporation (Novartis) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Pluvicto and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The TV ad includes the following representation (in pertinent part):

- **VO/CLOSED CAPTION:** "What do you do when things get tough? You don't give up." (frames one and two)

The TV ad also depicts men engaging in various activities that showcase their perseverance and eventual success, such as painting a portrait, helping a child learn to ride a bicycle, fishing, completing a puzzle, building a table, and training a dog. The totality of these representations makes the TV ad misleading by suggesting that despite trying and failing previous prostate cancer treatments, perseverance combined with taking Pluvicto will definitively result in a successful outcome in treating prostate cancer. However, according to the CLINICAL STUDIES section of the FDA-approved prescribing information (PI), 49% of the patients included in the PSMAfore trial had a confirmed overall response rate (ORR). We also note that of the 49% of patients who achieved an ORR, only 21% had a complete response. We acknowledge the disclaimer on frame 31 states, "Individual results may vary...;" however, this does not mitigate the misleading impression created by these representations.

The TV ad is misleading because it fails to provide material information regarding Pluvicto's full FDA-approved indication. Specifically, the INDICATIONS AND USAGE section of the PI states the following (in pertinent part, emphasis added):

> PLUVICTO is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibitor (ARPI) therapy, and
>
> • are considered appropriate to delay taxane-based chemotherapy…

The TV ad suggests the use of Pluvicto in adult patients with PSMA-positive mCRPC who have been treated with ARPI therapy, but it does not specify its use in patients who are considered appropriate candidates to delay taxane-based chemotherapy. By failing to adequately communicate the indication for Pluvicto, the TV ad creates a misleading impression about the drug's FDA-approved indication.

The TV ad is misleading because the attention-grabbing visuals and frequent scene changes (i.e., a man is seen working on a puzzle, a second man is building a table and having a tea party, and a third man is training a dog) during the presentation of the major statement interfere with comprehension of the major statement.

Conclusion and Requested Action

For the reasons described above, the TV ad misbrands Pluvicto 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 Novartis 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 Pluvicto that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Pluvicto.

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 587 in addition to the NDA 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 6592 under NDA 215833. 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 05:09:09 PM
On behalf of George Tidmarsh, M.D., Ph.D