ASTRO
TARGETING CANCER CARE

**AMERICAN SOCIETY FOR RADIATION ONCOLOGY**
251 18th St. South, 8th Floor
Arlington, VA 22202

**Main:** 703.502.1550
**Fax:** 703.502.7852
www.astro.org · www.rtanswers.org



March 15, 2023

Patrizia Cavazzoni, MD
Director, Center for Drug Evaluation and Research
US Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Cavazzoni:

On behalf of the American Society for Radiation Oncology[1], we are concerned about patient access to Lutetium LU 177 Vipivotide Tetraxetan (Pluvicto) and are writing to support Novartis' request for expedited review of their Milburn, New Jersey production facility. This facility produces Pluvicto, which is used to treat patients with PSMA-positive metastatic prostate cancer.

Currently, Novartis is shipping doses from their production facility in Italy to the United States. This facility is unable to meet demand, and patients are either not receiving their full treatment, or their treatment is being delayed. Further, Novartis notified providers that they are pausing all new patient starts until there is more supply. Given that Pluvicto must reach the patient within five days, if even one step in the shipping process is delayed or goes awry, the dose (or doses) will be wasted, and patients will have to wait even longer for treatment. This will have negative implications for patients for whom Pluvicto is their only option for effective therapy.

We respect the FDA's regulatory role in protecting patients by ensuring therapies are safe and effective. However, without a consistent and stable domestic source of Pluvicto, patients cannot receive the recommended course of treatment for this life-extending radiopharmaceutical. We believe that without expedited review and approval of Novartis' Milburn, NJ production facility, patient care will be compromised.

[1] ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science and advocacy. ASTRO's highest priority has always been ensuring patients receive the safest, most effective treatments.

We thank the FDA for their consideration and look forward to continuing to work with the Agency on this and other important matters. Should you have questions, please feel free to contact Cindy Tomlinson, Senior Manager for Patient Safety and Regulatory Affairs at 703.839.7366 or cindy.tomlinson@astro.org.

Sincerely,

Laura I. Thevenot
Chief Executive Officer

Geraldine M. Jacobson, MD, MBA, MPH, FASTRO
Chair

CC: Libero Marzella, MD, Director, Division of Imaging and Radiation Medicine, Center for Drug Evaluation and Research
Valerie Jensen, R.Ph., Associate Director of Drug Shortages, Center for Drug Evaluation and Research