SOCIETY OF NUCLEAR MEDICINE & MOLECULAR IMAGING

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Food and Drug Administration

Dear Drs Marzella, Amiri-Kordestani, and Valerie Jensen,

This letter is regarding the posting of Lutetium Lu 177 Vipivotide Tetraxetan (Pluvicto) Injection as “currently in shortage” by the FDA on March 7, 2023.

This letter is a request for rapid review of Novartis’ facility located in Milburn, New Jersey, to produce Pluvicto. We are writing as representatives of the Society of Nuclear Medicine and Molecular Imaging (SNMMI), to express the urgent clinical need for increased access to Pluvicto therapy for our prostate cancer patients in the USA. This letter is written with deep respect for the regulatory role the FDA plays in protecting our patients by ensuring therapies are safe and effective, and with understanding that the FDA has many critical and competing tasks and limited resources.

Novartis released a notice on March 2, 2023, stating that the filing to the FDA for the approval of the Milburn, NJ radioligand therapy manufacturing facility for commercial production of Pluvicto for patients in the USA has been completed.

Pluvicto is a lifesaving prostate cancer radioligand therapy currently used in patients with late-stage disease.

We are thrilled to have this new therapy to treat our patients and patients are anxious to start therapy. These patients have few, if any, options left for effective therapy. Unfortunately, with the current shortage, therapy doses are frequently cancelled, and therapy can be delayed for months. This situation can be catastrophic for patients, and some will not survive the delay.

In the last few weeks there has been a significant increase in the frequency of supply disruptions and on 2/26/23 we were informed that at this time, no new patients would be allowed to begin a course of Pluvicto therapy.

Novartis is operating at maximum capacity in production facilities in Italy and ships Pluvicto to the US. Pluvicto is a radioactive therapy that degrades over time and must be used within about 5 days of production, or it must be disposed. In this scenario, if there are any production failures, or other supply chain issues, patients are affected, and doses are cancelled. There is very limited redundant or extra production capacity to give to patients whose doses have been cancelled. We often are dealing with frail patients, who may have traveled some distance to get to a center that provides Pluvicto, only to find out there will be no dose available and then have to wait to learn when the dose can be rescheduled. This happens to many of our patients every week.

At the same time, there remains a risk of further disruptions due to production failures. In this scenario, Novartis has decided to delay starting therapy for new patients. In theory, this will minimize further disruptions and allow for rescheduling of therapy doses for patients whose doses have been disrupted. However, this change effectively blocks new patients from access to Pluvicto for many months. It appears these issues have impacted every center in the US that performs Pluvicto therapy.

We are requesting a rapid review of the submission related to the Milburn facility to ensure that it meets all necessary standards for the production of Pluvicto. We understand the importance of ensuring that medications are safe and effective, and we are committed to working with the FDA to ensure that this is the case.

Thank you for your attention to this matter, and we look forward to hearing from you soon.

Sincerely,

M. Ghesani

Munir Ghesani, MD
President, Society of Nuclear Medicine and Molecular Imaging