Sample Letter to FDA – Pluvicto Shortage

Please describe who you are and where you practice! For example, the letter may be on letterhead and the introductory sentence could say, for example, "*We are a busy practice of 5 doctors who see x patients a day…We are writing….*"

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

I am/We are writing regarding the posting of Lutetium Lu 177 Vipivotide Tetraxetan (Pluvicto) Injection as "currently in shortage" by the FDA on March 7, 2023.

I would like to request a rapid review of Novartis' facility located in Milburn, New Jersey, to produce Pluvicto. There is an urgent clinical need for increased access to Pluvicto therapy for prostate cancer patients in the United States. As a member of the nuclear medicine community, I appreciate the important role of the FDA in protecting patients by ensuring therapies are safe and effective.

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

(*If relevant, provide a personal example from your practice*)

Recently, we were informed that at this time, no new patients can begin Pluvicto therapy. Novartis is operating at maximum capacity in production facilities in Italy, and Pluvicto for American patients must be shipped from there to the United States. Pluvicto is a radioactive therapy that degrades over time, so

it must be used within about 5 days of production. If there are production failures or other supply chain issues that delay delivery, then doses expire and must be discarded, and patients must wait until more become available. We often are dealing with frail patients who may have traveled long distances to get to a center that provides Pluvicto—only to find that no doses are available and then have to wait until the dose can be rescheduled. It appears that these issues have impacted every center in the United States that performs Pluvicto therapy.

We are requesting a rapid review of the submission to ensure that the Milburn facility meets all necessary standards for production of Pluvicto.

Thank you for your consideration.