Radioligand Therapy Supply Information

Find radioligand therapy (RLT) supply updates for the United States (US) from Novartis, including contact information for questions.

Jan 05, 2024

Novartis has received approval from the US Food and Drug Administration (FDA) for commercial manufacturing of Pluvicto® (lutetium Lu 177 vipivotide tetraxetan) at its new large-scale, state-of-the-art radioligand therapy (RLT) manufacturing facility in Indianapolis, Indiana, United States. The 70,000-square foot site, the company's second US location, is designed specifically for RLT manufacturing and is now the largest and most advanced Novartis facility of its kind in the world.

The Indianapolis site represents the next phase of RLT manufacturing growth as this new addition brings substantial supply increases for the foreseeable future.

Read the full announcement

Oct 26, 2023

The US Food and Drug Administration (FDA) has classified the Pluvicto® (lutetium Lu 177 vipivotide tetraxetan) drug shortage status as resolved. This determination is the result of efforts to significantly scale up production of Pluvicto that have more than doubled weekly production capacity since May. Novartis is committed to providing a consistent, reliable supply of Pluvicto and making this important medicine readily available to patients.

Read the full announcement

Jun 09, 2023

We received US Food and Drug Administration (FDA) approval in April to add our RLT manufacturing facility in Millburn, New Jersey, as an approved site for the US commercial production of Pluvicto. We are ahead of schedule in the acceleration of production and are accepting orders for all doses within the Pluvicto treatment cycle. Supply availability will continue to increase throughout the year as we further expand our RLT manufacturing capacity at our facilities, helping to ensure stable, reliable supply of Pluvicto.

April 21, 2023

Novartis has received US Food and Drug Administration approval to begin supplying Pluvicto® (lutetium Lu 177 vipivotide tetraxetan) for US commercial use from the Novartis RLT manufacturing facility in Millburn, New Jersey. Production will begin in the coming weeks and gradually ramp up. The site is expected to contribute meaningfully to supply in the third quarter after the anticipated approval of additional lines at the site.

Read the full announcement

March 09, 2023

Novartis has been experiencing challenges supplying the current demand for Pluvicto® (lutetium Lu 177

vipivotide tetraxetan). We have notified health care providers and treatment centers in the US about these challenges and are actively engaging with them to manage rescheduling of patient doses. Patients who are currently in our scheduling system and awaiting their first doses will need to be rescheduled. We also are taking the difficult but necessary step to pause on accepting new patient starts until we have more supply.

Pluvicto is currently manufactured at our facility in Ivrea, Italy, in batches with only a 5-day window for each dose to reach its intended patient. Any interruption in the process, from unplanned manufacturing events to doses not arriving in time, may result in patient doses being rescheduled, which has a cascading effect on patients scheduled for future treatment.

At this time, our priority is to supply patients who have received their first doses and are currently in the treatment process. This is important to allow patients who have already begun the treatment cycle to appropriately complete their course of therapy. We continue to ship as many doses as we can to treat as many patients as possible and our clinical trial programs are ongoing.

We also are working to significantly increase Pluvicto supply over the next 12 months. We completed our filing to the US Food and Drug Administration in February for approval of the Millburn site for commercial production of Pluvicto for US patients and have requested an expedited review from the agency. Pending approval, Millburn could begin supplying Pluvicto by this summer, expanding our current manufacturing capacity. We also are building a new facility in Indianapolis that could be operational as soon as the end of this year, which will add significant commercial supply of Pluvicto.

We recognize that any rescheduled dose is distressing for patients and their loved ones and poses challenges for the treatment centers. We are striving to serve as many patients as possible as quickly as possible as we work through the current situation. For questions or feedback, please contact 1 888 NOW NOVA (1 888 669 6682).

Patient FAQs

Answering your questions about PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) supply

Contact Information

1 888 NOW NOVA (1 888 669 6682)

Resources

RLT Manufacturing Fact Sheet (PDF 0.2MB)

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