# FDA approves Novartis Millburn facility for US commercial production of Pluvicto®

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Novartis has received US Food and Drug Administration (FDA) approval to begin supplying Pluvicto for US commercial use from the Novartis Radioligand Therapy (RLT) manufacturing facility in Millburn, New Jersey. Production will begin in the coming weeks and ramp up gradually. The site is expected to contribute meaningfully to supply and sales in the third quarter, after the anticipated approval of additional lines at the site. Capacity should continue to increase through the second half of this year, helping to ensure stable, reliable supply to patients. The RLT manufacturing facility in Ivrea, Italy, will continue to supply the US market, and further capacity expansion is underway at the site.

A new facility in Indianapolis, Indiana, is nearing completion, and is expected to open as soon as the end of this year. In addition, Novartis has received approval for the Zaragoza, Spain, site to supply the EU market. We expect this site to ramp up gradually over the coming months.

With these sites, a capacity of at least 250k doses of Pluvicto annually is targeted in 2024+.

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