Novartis completes FDA filing for approval of Millburn facility to support Pluvicto® launch

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Novartis has completed its filing to the FDA for approval of the Millburn, NJ radioligand therapy manufacturing facility for commercial production of Pluvicto for US patients, and has requested an expedited review from the agency. Pending FDA approval, Millburn could begin supplying Pluvicto by this summer, expanding our current manufacturing capacity.

We also are building a new facility in Indianapolis which could be operational as soon as the end of this year, which will add significant commercial supply of Pluvicto for US patients.

With these sites, we are targeting a capacity of at least 250k doses of Pluvicto annually in 2024.
