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MEDIA UPDATE

Novartis resumes production and delivery of radioligand therapy medicines ahead of schedule

- *Production and phased deliveries of patient doses resumed in early June*
- *Screening and enrollment have restarted for ^{177}Lu-PSMA-617 and Lutathera® clinical trials*
- *Expanding radioligand therapy manufacturing capacity globally to support demand*

Basel, June 30, 2022 — In early June, Novartis restarted radioligand therapy (RLT) production at its sites in Ivrea, Italy, and Millburn, New Jersey, and resumed delivery of doses to patients in a phased approach, ahead of the expected six-week timeframe. The company has remediated the issues that led to the temporary, voluntary suspension of production in May. These issues did not affect patient safety, and no risk to patients from the doses previously produced at these sites was identified.

Novartis has also restarted screening and enrollment for clinical trials with ^{177}Lu-PSMA-617 (INN: lutetium (177Lu) vipivotide tetraxetan), marketed as Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan) in the US, in most countries globally, and clinical trials with Lutathera® (USAN: lutetium Lu 177 dotatate; INN: lutetium (177Lu) oxodotreotide) in the US and Canada.

In addition, to support the growing demand for our RLT platform, Novartis is investing in the expansion of RLT production capabilities in both Millburn and Ivrea, as well as building a new radioligand manufacturing facility in Indianapolis, Indiana that will be operational in 2023.

We recognize that this situation has affected – and is still affecting – patients, their families and care teams. Product quality and patient safety remain the company's top priorities. We expect that product supply may be initially limited, and we are working hard to resume full production capacity and meet patient demand as quickly as possible. We continue to communicate with health authorities, and they are aware that we have restarted production and that the delivery of patient doses has resumed.

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