

MEDIA UPDATE

Novartis provides update on production of radioligand therapy medicines

- *Novartis has temporarily suspended production of Lutathera® and Pluvicto™/ ¹⁷⁷Lu-PSMA-617 at facilities in Ivrea, Italy and Millburn, New Jersey*
- *This action has been taken out of an abundance of caution as a result of potential quality issues identified in its manufacturing processes*
- *The production suspension impacts commercial and clinical trial supply*
- *Current expectation is resolution of these issues, and resumption of some supply, within 6 weeks; subject to confirmation via an ongoing review*

Basel, May 5, 2022 — Novartis today announced a temporary, voluntary suspension of production at its radioligand therapy production sites in Ivrea, Italy and Millburn, New Jersey. The company has taken this action out of an abundance of caution as it addresses potential quality issues identified in its manufacturing processes. Novartis is conducting a thorough review of the situation and currently expects to resolve the issues and resume some supply in the next six weeks.

As a result, the company is temporarily suspending delivery of Lutathera® (USAN: lutetium Lu 177 dotatate; INN: lutetium (177Lu) oxodotreotide) in the US and Canada, and ¹⁷⁷Lu-PSMA-617 (INN: lutetium (177Lu) vipivotide tetraxetan), marketed as Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan) in the US. Some doses of Lutathera® (lutetium (177Lu) oxodotreotide) will be available in Europe and Asia from Novartis radioligand therapy production site in Zaragoza, Spain, although there may be some delays in supply.

In addition, Novartis is putting a temporary hold on screening and enrollment for ¹⁷⁷Lu-PSMA-617 clinical trials globally, and Lutathera clinical trials in the US and Canada.

Quality and patient safety are our top priorities. There is currently no indication of any risk to patients from doses previously produced at these sites. Novartis has notified treatment sites to closely monitor patients who have recently been injected and asked them to report any adverse events to Novartis patient safety.

We recognize that this situation affects patients, their families and care teams. Novartis takes this very seriously and the company is doing everything it can to resolve this issue and resume patient doses as quickly as possible. Health authorities have been informed and will receive additional updates as they are available.

Disclaimer

This media update contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potential,” “can,” “will,” “plan,” “may,” “could,” “would,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this media update, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this media update will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this media update as of this date and does not undertake any obligation to update any forward-looking statements contained in this media update as a result of new information, future events or otherwise.

About Novartis

Novartis is reimagining medicine to improve and extend people’s lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world’s top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 108,000 people of more than 140 nationalities work at Novartis around the world. Find out more at <https://www.novartis.com>.

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