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MEDIA & INVESTOR RELEASE

Novartis expands production of Pluvicto™ with addition of its largest and most advanced radioligand therapy manufacturing facility in Indianapolis

- *FDA approval of the company's second US Radioligand Therapy (RLT) manufacturing facility increases RLT production capacity to 250,000 doses in 2024 and beyond*
- *New 70,000-square foot RLT facility is the company's largest and most advanced in the world to date and centrally located in the US to maximize access for patients and treatment centers*
- *With four active RLT manufacturing sites and unconstrained supply, Novartis can sufficiently meet current and future demand as ongoing clinical trials may present the potential to bring Pluvicto and Lutathera® to more patients in earlier lines of treatment*
- *Novartis is investigating a broad portfolio of RLTs in advanced cancers including breast, colon, neuroendocrine, lung, pancreatic and prostate to continue meeting global patient needs*

Basel, January 5, 2024— Novartis announced today that it has received approval from the US Food and Drug Administration (FDA) for commercial manufacturing of Pluvicto™ (INN: lutetium (^{177}Lu) vipivotide tetraxetan / USAN: 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.

"The intricate process of providing RLTs to patients within hours of production requires precision manufacturing expertise to bring these medicines to individuals who critically need them," said Steffen Lang, President, Operations, Novartis. "Adding a second US RLT facility, our largest and most advanced yet, into our manufacturing network underscores our commitment to ensure a consistent and reliable experience for patients and their healthcare teams for years to come. We also recently announced plans to build our manufacturing capabilities in Sasayama, Japan and Haiyan, Zhejiang, China, as we continue to look for opportunities to further expand our worldwide reach."

The Indianapolis facility, centrally located within the US, is purpose-built from the ground up to manufacture RLTs now and into the future and includes space for continued line expansion including plans for fully automated lines, a first for the radiopharmaceutical industry. The new site will supply the growing demand for patients in the US and eventually in Canada, upon approval, together with the company's Millburn, New Jersey location. The site in Ivrea, Italy will continue to supply patients in and outside the US while the facility in Zaragoza, Spain will solely provide RLTs for patients outside the US.

Novartis recently announced that supply of Pluvicto is unconstrained. Having doubled weekly production, Novartis currently has more than sufficient supply to treat patients within two weeks of diagnosis, which is important for these patients with advanced disease who may need treatment quickly.

Novartis is committed to improving access to its RLTs, Pluvicto and Lutathera® (INN: lutetium (^{177}Lu) oxodotreotide / USAN: lutetium Lu 177 dotatate) by adding more treatment sites in closer proximity to patients over the coming months.

With four active manufacturing facilities, and a RLT production capacity of 250,000 doses in 2024 and beyond, Novartis continues to expand its worldwide RLT manufacturing network as ongoing clinical trials may present the potential to bring Pluvicto and Lutathera to more patients in earlier lines of treatment.

Novartis and Radioligand Therapy (RLT)
Novartis is committed to expanding the radioligand therapy platform to shape the future of RLT as a treatment class. By harnessing the power of radioactive atoms and applying it to advanced cancers, RLT is theoretically able to deliver radiation to target cells anywhere in the body[1,2].

We are investigating a broad portfolio of RLTs, exploring new isotopes, ligands and combination therapies to look beyond gastroenteropancreatic neuroendocrine tumors (GEP-NETs) and prostate cancer and into breast, colon, lung and pancreatic cancer.

Novartis recently presented data at the 2023 European Society for Medical Oncology (ESMO) Congress studying Pluvicto in the pre-taxane setting for patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistance prostate cancer (mCRPC).

With established global expertise, and specialized supply chain and manufacturing capabilities across its network, we are supporting growing demand for our RLT medicines. Our production capabilities continue to expand and now include sites in Millburn, US, Zaragoza, Spain, Ivrea, Italy and our new state-of-the-art facility in Indianapolis, US. We recently announced plans to expand our manufacturing capabilities and build additional points of supply in Sasayama, Japan and Haiyan, Zhejiang, China to produce RLTs for patients in Japan and China. We are continually evaluating additional opportunities to increase capacity around the world.

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About Novartis
Novartis is an innovative medicines company. Every day, we work to reimagine medicine to improve and extend people's lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach more than 250 million people worldwide.

Reimagine medicine with us: Visit us at **https://www.novartis.com** and connect with us on **LinkedIn, Facebook, X/Twitter** and **Instagram.**

References

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