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MEDIA & INVESTOR RELEASE

Novartis radioligand therapy Lutathera® FDA approved as first medicine specifically for pediatric patients with gastroenteropancreatic neuroendocrine tumors

- *Approval based on NETTER-P trial in which Lutathera demonstrated a consistent safety profile and comparable drug exposure between pediatric (ages 12-17) and adult patients*

- *Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) are a rare cancer that is often unresectable and commonly diagnosed in the late stages of disease*

- *Novartis, a leader in radioligand therapy (RLT), is investigating a portfolio of RLTs to treat a broad range of cancers, including GEP-NETs, lung, prostate, breast, colon, brain and pancreatic cancers*

Basel, April 23, 2024 – Novartis today announced that the U.S. Food and Drug Administration (FDA) approved Lutathera® (USAN: lutetium Lu 177 dotatate / INN: lutetium (177Lu) oxodotreotide) for the treatment of pediatric patients 12 years and older with somatostatin receptor-positive (SSTR+) gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut NETs. This approval makes Lutathera the first therapy specifically reviewed and approved for use in pediatric patients with GEP-NETs.

“Lutathera is now the very first therapy approved specifically for children with GEP-NETs, offering new hope to young patients living with this rare cancer,” said Tina Deignan, Therapeutic Area Head, Oncology US. “Radioligand therapies have extraordinary potential to shape the future of cancer care. With this approval, we have taken another vital step toward fulfilling that vision, strengthening our commitment to researching and developing the RLT platform across multiple cancer types and treatment settings.”

NETs are a type of cancer that originates in neuroendocrine cells throughout the body and are commonly considered slow-growing malignancies[1]. The diagnosis of NETs is often delayed due to the inactive nature of the disease, and approximately 10% to 20% of pediatric patients are diagnosed with metastatic disease[2,3]. Even though NETs are an orphan disease, their incidence has increased over the past several decades[1,4-6].

“While GEP-NETs in children and adolescents are rare, the impact can be devastating. Today’s approval addresses a critical need for new treatment options for these vulnerable patients,” said Dr. Theodore Laetsch, trial investigator and Director, Developmental Therapeutics Program, Children’s Hospital of Philadelphia (CHOP), a NETTER-P clinical trial site. “The introduction of radioligand therapy significantly advanced how we treat GEP-NETs,

and I'm encouraged that younger patients now have the potential to benefit from this innovation."

The approval was based on the NETTER-P trial, which evaluated Lutathera in patients aged 12 to <18 years old with SSTR+ GEP-NETs[7]. The study reported a safety profile consistent with the adult population studied in NETTER-1, the pivotal trial for approval of Lutathera in adults. In addition, the estimated radiation absorbed dose in pediatric patients was within established organ thresholds for external beam radiation and comparable to that in adults for the approved dose.

About Lutathera®
Lutathera® (lutetium Lu 177 dotatate) is approved in the US for the treatment of adults and children 12 years and older with SSTR-positive GEP-NETs, including those in the foregut, midgut and hindgut, an indication which includes the populations studied in the randomized, controlled Phase III trials NETTER-1 and NETTER-2. Lutathera is also approved in Europe for unresectable or metastatic, progressive, well-differentiated (G1 and G2), SSTR-positive GEP-NETs in adults, and in Japan for SSTR-positive NETs[8,9].

Novartis and Radioligand Therapy (RLT)
Novartis is reimagining cancer care with RLT for patients with advanced cancers. 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[10,11].

Novartis is 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.

With established global expertise, and specialized supply chain and manufacturing capabilities across the Novartis 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.

Disclaimer
This press release 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 press release, 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 press release 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; 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 press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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**.

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