Novartis confirms unconstrained supply for Pluvicto® and continues to significantly expand the number of treatment centers

Oct 26, 2023

- *US FDA has classified drug shortage status as resolved*[1]
- *Novartis capacity to produce Pluvicto will continue to grow with anticipated expansions to the manufacturing network in the US and globally*
- *More than 200 centers are actively ordering doses of Pluvicto for patients in need, with plans to onboard approximately 130 more*

East Hanover, October 26, 2023 — Novartis today announced that the US Food and Drug Administration has classified the Pluvicto® (lutetium Lu 177 vipivotide tetraxetan) drug shortage status as resolved. This determination is the result of efforts to significantly scale up production of Pluvicto that have more than doubled weekly production capacity since May. Novartis is committed to providing a consistent, reliable supply of Pluvicto and making this important medicine readily available to patients.

“We have been working hard to increase the capacity and improve the reliability of the supply of our radioligand therapies to ensure patients have access to this therapy and to prepare for future growth as more patients may become eligible for this treatment,” said Victor Bulto, President, Novartis US. “Radioligand therapies have the potential to shift the standard of care in oncology and we are excited about the possibilities of our broad RLT pipeline for patients. With substantial experience in developing a reliable supply chain and delivery infrastructure, we are well positioned to expand access to these therapies for years to come.”

Following FDA approval for commercial production of Pluvicto at the Novartis RLT manufacturing facility in Millburn, New Jersey earlier this year, supply is now 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. Pluvicto supply availability should continue to increase into 2024 as Novartis builds additional capacity by expanding production lines at the Millburn, New Jersey site, as well as the new state-of-the-art RLT facility in Indianapolis, Indiana. This site has started clinical production of Pluvicto and, pending FDA approval, will also manufacture commercial doses.

Novartis is expanding access to its RLTs in the US by partnering with treatment sites to add more central locations for patients. As of October, there are more than 200 facilities in the US certified to administer the company’s RLTs. Novartis plans to onboard approximately 130 more certified facilities, strengthening access for more eligible patients across the country.

The company’s RLT manufacturing facility in Ivrea, Italy will continue to supply patients in and outside the US while the facility in Zaragoza, Spain will solely supply patients outside of the US, and Novartis has a vision to add more RLT manufacturing locations around the world. With four active facilities by 2024 and an anticipated combined annual capacity target of at least 250,000 RLT doses in 2024 and beyond, Novartis is committed to

providing adequate supply for current and future demand as ongoing clinical trials may present the potential to bring Pluvicto to more patients.

About Pluvicto® (lutetium Lu 177 vipivotide tetraxetan)

Pluvicto is an intravenous radioligand therapy (RLT) combining a targeting compound (a ligand) with a therapeutic radionuclide (a radioactive particle, in this case lutetium-177)[2,3]. After administration into the bloodstream, Pluvicto binds to target cells, including prostate cancer cells that express PSMA, a transmembrane protein[2,3]. Once bound, energy emissions from the radioisotope damage the target cells and nearby cells, disrupting their ability to replicate and/or triggering cell death[3].

Pluvicto is approved in the U.S., the E.U. and other countries to treat adults with a type of advanced cancer called PSMA-positive mCRPC and who have already been treated with other anticancer treatments (ARPI and taxane-based chemotherapy)[4-8]. These regulatory decisions are supported by the results from the pivotal Phase III VISION trial, where Pluvicto met both primary endpoints of OS and rPFS, reducing the risk of death by 38% and the risk of radiographic progression or death by 60% compared to standard of care[2].

As part of our goal to move into earlier stages of disease, we have multiple Phase III studies to evaluate Pluvicto in earlier lines of treatment for PSMA-positive prostate cancer: PSMAfore (NCT04689828) is ongoing in pre-taxane mCRPC, PSMAddition (NCT04720157) is ongoing in the metastatic hormone-sensitive setting and PSMA-DC (NCT05939414) in the oligometastatic setting is in preparation. More information on these studies may be found at www.clinicaltrials.gov.

Novartis and Prostate Cancer

With more than 1.4 million new cases and 375,000 deaths in 2020 alone, prostate cancer is the most frequently diagnosed cancer in men in 112 countries – more than half the world[9].

At Novartis, we are harnessing the innovation of our world-class scientists, strategic partnerships and one of the industry's most competitive pipelines to explore the potential of new, targeted therapies and precision medicine platforms to address the greatest unmet needs in prostate cancer.

Our goal is to reduce the global disease burden, extend the lives of patients with prostate cancer and elevate current standards of care.

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.

Novartis has established global expertise, specialized supply chain and manufacturing capabilities across its network of RLT production sites. In order to support growing demand for our RLT platform, we have expanded our production capabilities in Millburn, New Jersey (U.S.), Zaragoza (Spain) and Ivrea (Italy) and have a new-state-of-the art facility in Indianapolis, Indiana (U.S.), which is expected to open in the coming months, pending approval from the U.S. Food and Drug Administration (FDA). We are continually evaluating additional opportunities to expand capacity around the world.

Important Safety Information

Use of PLUVICTO involves exposure to radioactivity. Long-term, accruing radiation exposure is associated with increased risk for cancer. To minimize radiation exposure to others following administration of PLUVICTO, patients are advised to limit close contact (less than 3 feet) with household contacts for 2 days or with children and pregnant women for 7 days, to refrain from sexual activity for 7 days, and to sleep in a separate bedroom from household contacts for 3 days, from children for 7 days, or from pregnant women for 15 days.

PLUVICTO may cause low level of blood cell counts. Patients should tell their doctor right away if they develop any new or worsening symptoms, including tiredness or weakness, pale skin, shortness of breath, bleeding or bruising more easily than normal or difficulty to stop bleeding, or frequent infections with signs such as fever, chills, sore throat, or mouth ulcers. PLUVICTO may also cause problems with kidneys. Patients should tell their doctor right away if they develop any new or worsening symptoms, including passing urine less often or passing much smaller amounts of urine than usual.

Before receiving PLUVICTO, patients should tell their doctor if they have low level of blood cell counts (hemoglobin, white blood cell count, absolute neutrophil count, platelet count); if they have or have had tiredness, weakness, pale skin, shortness of breath, bleeding or bruising more easily than normal or difficulty stopping bleeding, or frequent infections with signs such as fever, chills, sore throat, or mouth ulcers (possible signs of myelosuppression); if they have or have had kidney problems; if they have or have had any other type of cancer or treatment for cancer, as PLUVICTO contributes to long-term cumulative radiation exposure; and if they are sexually active, as all radiopharmaceuticals, including PLUVICTO, have the potential to cause harm to an unborn baby. Patients should use effective contraception for intercourse during treatment with PLUVICTO and for 14 weeks after the last dose. PLUVICTO may cause temporary or permanent infertility.

Before administration of PLUVICTO patients should drink plenty of water in order to urinate as often as possible during the first hours after administration.

The most common side effects of PLUVICTO include tiredness, dry mouth, nausea, low red blood cell count, loss of appetite, changes in bowel movements (constipation or diarrhea), vomiting, low blood platelet count, urinary tract infection, weight loss, and abdominal pain.

Please see full Prescribing Information for PLUVICTO at https://www.novartis.us/sites/www.novartis.us/files/pluvicto.pdf.

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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,” “seek,” “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 a focused 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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