Lantheus Announces Acceptance of its First-to-File ANDA for Generic LUTATHERA® (Lutetium Lu 177 Dotatate)

Jan 11, 2024

BEDFORD, Mass., Jan. 11, 2024 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. (“Lantheus” or the “Company”) (NASDAQ: LNTH), the leading radiopharmaceutical-focused company committed to enabling clinicians to Find, Fight and Follow disease to deliver better patient outcomes, today announced that its Abbreviated New Drug Application (ANDA) for Lutetium Lu 177 Dotatate (^{177}Lu-PNT2003), a generic version of LUTATHERA® (lutetium Lu 177 dotatate), has been accepted for filing by the U.S. Food and Drug Administration (FDA), marking a pivotal moment in the Company’s commitment to improve patient outcomes. LUTATHERA® is indicated for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults.

Based on the most recent update to the FDA’s online paragraph IV database listings, [1] Lantheus believes it is the first applicant to have filed a substantially complete ANDA for Lutetium Lu 177 Dotatate containing a Paragraph IV certification under the provisions of the Hatch-Waxman Act. Should its ANDA be approved by the FDA, Lantheus believes it will be eligible for 180 days of generic marketing exclusivity in the U.S.

Lantheus licensed exclusive worldwide commercialization rights (excluding certain Asian territories) to ^{177}Lu-PNT2003 from POINT Biopharma Global, Inc. in December of 2022. To read the press release announcing that licensing transaction, please click here.

About Lantheus
Lantheus is the leading radiopharmaceutical-focused company, delivering life-changing science to enable clinicians to Find, Fight and Follow disease to deliver better patient outcomes. Headquartered in Massachusetts with offices in New Jersey, Canada and Sweden, Lantheus has been providing radiopharmaceutical solutions for more than 65 years. For more information, visit www.lantheus.com.

Safe Harbor for Forward-Looking and Cautionary Statements
This press release contains “forward-looking statements” that are subject to risks and uncertainties. Forward-looking statements include, but are not limited to, statements relating to the potential FDA approval of and potential generic marketing exclusivity relating to PNT2003 and statements regarding Lantheus’ expectations, hopes, beliefs, intentions or strategies regarding the future. Forward-looking statements may be identified by their use of terms such as “should,” “believe” and other similar terms. Such forward-looking statements are based upon current plans, estimates and expectations that are subject to risks and uncertainties that could cause actual results to materially differ from those described in the forward-looking statements.

LUTATHERA® is a registered trademark of Novartis AG and/or its affiliates.

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[1] See FDA's list of drug products for which an ANDA has been received by the Office of Generic Drugs containing a "Paragraph IV" patent certification.

Source: Lantheus Holdings, Inc.