Lantheus and POINT Biopharma Announce FDA Grants Fast Track Designation for ^{177}Lu-PNT2002 for the Treatment of Metastatic Castration Resistant Prostate Cancer

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BEDFORD, Mass. and INDIANAPOLIS, April 24, 2023 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. (“Lantheus”) (NASDAQ: LNTH), a company committed to improving patient outcomes through diagnostics, radiotherapeutics and artificial intelligence solutions that enable clinicians to Find, Fight and Follow disease, and POINT Biopharma Global, Inc. (“POINT”) (NASDAQ: PNT), a company accelerating the discovery, development and global access to life-changing radiopharmaceuticals, today announced the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for ^{177}Lu-PNT2002 for the treatment of metastatic castration resistant prostate cancer (mCRPC). Fast track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and address unmet medical needs. PNT2002 is an innovative PSMA-targeted ^{177}Lu-based radiopharmaceutical therapy that combines a PSMA-targeted ligand, PSMA-I&T, with the beta-emitting radioisotope no-carrier-added ^{177}Lu.

“Fast track designation by the FDA is an important milestone and recognizes the potential for ^{177}Lu-PNT2002 to address the significant unmet need for mCRPC patients,” said Jean-Claude Provost, M.D., Chief Medical Officer at Lantheus. “We are encouraged by the FDA’s decision as it reflects the need for FDA approved and widely available treatments for these patients. This designation will allow us to work closely with the FDA, along with our partner POINT, to quickly advance ^{177}Lu-PNT2002, with the potential to make a meaningful difference for patients who require new treatment options.”

“The FDA Fast Track designation for ^{177}Lu-PNT2002 underscores its potential to address a serious unmet need and serve as a meaningful therapeutic option for patients with mCRPC,” said Dr. Neil Fleshner, M.D., Chief Medical Officer of POINT Biopharma. “We are seeing that radioligand therapy is quickly becoming another pillar of cancer treatment, and, with our continued focus on supply chain excellence, we believe that we are very well positioned to meet market demands post approval. We will continue to work closely with our partner Lantheus and with the FDA to bring ^{177}Lu-PNT2002 to patients as quickly as possible.”

The Phase 3 SPLASH trial is a multi-center, randomized, open label assessment of ^{177}Lu-PNT2002 in participants with PSMA-expressing mCRPC who have progressed on androgen receptor pathway inhibitor therapy and refuse, or are not eligible for, chemotherapy. Participants were randomized 2:1 with those in arm A receiving ^{177}Lu-PNT2002 and those in arm B receiving either abiraterone or enzalutamide. Participants in arm B who experience centrally assessed radiographic progression and meet protocol eligibility have the option to crossover and receive ^{177}Lu-PNT2002. Patients are subject to follow-up for up to 5 years from their first ^{177}Lu-PNT2002 dose. The primary endpoint of the study is radiographic progression-free survival. Key secondary endpoints include overall survival, overall response rate, and duration of response. Safety and tolerability will also be assessed. Enrollment in the trial is complete and SPLASH top line data is expected in the second half of 2023. More information about the trial is accessible at www.ClinicalTrials.gov, identifier NCT04647526.

Lantheus in-licensed exclusive worldwide commercialization rights (excluding certain Asian territories) to ^{177}Lu-PNT2002 from POINT in December of 2022. To read the press release, please click here.

About Lantheus
With more than 65 years of experience in delivering life-changing science, Lantheus is committed to improving patient outcomes through diagnostics, radiotherapeutics and artificial intelligence solutions that enable clinicians to Find, Fight and Follow disease. Lantheus is headquartered in Massachusetts and has offices in New Jersey, Canada and Sweden. For more information, visit www.lantheus.com.

About POINT Biopharma Global Inc.
POINT Biopharma Global Inc. is a globally focused radiopharmaceutical company building a platform for the clinical development and commercialization of radioligands that fight cancer. POINT aims to transform precision medicine by combining a portfolio of targeted radioligand assets, a seasoned management team, an industry-leading pipeline, in-house manufacturing capabilities, and secured supply for medical isotopes including actinium-225 and lutetium-177. POINT’s active clinical trials include FRONTIER, the Phase 1 trial for PNT2004, a pan-cancer program targeting fibroblast activation protein-α (FAP-α), and SPLASH, the Phase 3 trial for ^{177}Lu-PNT2002 for people with metastatic castration resistant prostate cancer (mCRPC) after second-line hormonal treatment. Learn more about POINT Biopharma Global Inc. at https://www.pointbiopharma.com/.

Safe Harbor for Forward-Looking and Cautionary Statements
This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of

1995, as amended, that are subject to risks and uncertainties and are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements may be identified by their use of terms such as “advancing,” “aim,” “believe,” "continue,” “could,” “creates,” encouraged,” "expected,” “expects,” “looks,” “may,” “plans,” “positioned,” “potential,” “will,” “would” 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. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Readers are cautioned not to place undue reliance on the forward-looking statements contained herein, which speak only as of the date hereof. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law. Risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements include (i) the timing and potential outcomes of clinical studies, including POINT’s Phase 3 SPLASH trial for PNT2002 and the OZM-067 study for PNT2003; (ii) a delay in obtaining, or failure to obtain, a positive regulatory outcome from the FDA and regulatory authorities for PNT2002 and PNT2003; (iii) Lantheus’ ability to successfully launch PNT2002 or PNT2003 as commercial products; (iv) the market receptivity to PNT2002 or PNT2003 as radiopharmaceutical therapies; (v) the existence, availability and profile of competing products and therapies; (vi) our ability to obtain and maintain adequate coding, coverage and payment for PNT2002 and PNT2003; (vii) the safety and efficacy of PNT2002 and PNT2003; (viii) the intellectual property protection of PNT2002 and PNT2003; (ix) POINT’s ability to successfully develop, scale and maintain the manufacturing capabilities to support the launch and commercialization of PNT2002 and PNT2003; and (x) the risks and uncertainties discussed in Lantheus’ and POINT’s filings with the Securities and Exchange Commission (including those described in the Risk Factors section in their Annual Reports on Form 10-K and their Quarterly Reports on Form 10-Q).

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