Lantheus and POINT Biopharma Announce Positive Topline Results from Pivotal SPLASH Trial in Metastatic Castration-Resistant Prostate Cancer

December 18, 2023 at 7:30 AM EST

Phase 3 SPLASH study of ^{177}Lu-PNT2002 demonstrated statistically significant improvement in radiographic progression-free survival (rPFS)

BEDFORD, Mass., and INDIANAPOLIS, Dec. 18, 2023 (GLOBE NEWSWIRE) -- December 18, 2023 – Lantheus Holdings, Inc. (Lantheus) (NASDAQ: LNTH) and POINT Biopharma Global Inc. (POINT) (NASDAQ: PNT) today announced statistically significant topline results from the pivotal Phase 3 SPLASH study evaluating the efficacy and safety of ^{177}Lu-PNT2002, a prostate-specific membrane antigen (PSMA)-targeted radioligand therapy (RLT), in patients with metastatic castration-resistant prostate cancer (mCRPC) after progression on an androgen receptor pathway inhibitor (ARPI).

“There is an urgent unmet need for targeted treatment options for mCRPC patients, particularly for those whose cancer has progressed on androgen receptor pathway inhibitors,” said Dr. Kim Chi, SPLASH Principal Investigator, Medical Oncologist, BC Cancer. “The SPLASH study results demonstrate that ^{177}Lu-PNT2002 is well-tolerated and has the potential to play an important role in addressing those needs for patients with chemotherapy-naïve mCRPC.”

The SPLASH trial met its primary endpoint, demonstrating a median radiographic progression-free survival (rPFS) per blinded independent central review of 9.5 months for patients treated with ^{177}Lu-PNT2002, compared to 6.0 months for patients treated with ARPI in the control arm, a statistically significant 29% reduction in the risk of radiographic progression or death (hazard ratio [HR] 0.71; p=0.0088). At the time of the analysis, interim overall survival (OS) results were immature (46% of protocol-specified target OS events reached), the HR was 1.11. The companies expect additional, follow-up data in 2024 prior to the potential submission of a New Drug Application (NDA).

^{177}Lu-PNT2002 demonstrated a favorable safety profile with grade ≥3 treatment-emergent adverse events (TEAEs) per Common Terminology Criteria for Adverse Events (CTCAE), serious TEAEs, and TEAEs leading to discontinuation occurring at lower rates in the ^{177}Lu-PNT2002 arm than in the ARPI arm (30.1%, 17.1%, and 1.9% vs. 36.9%, 23.1%, and 6.2%, respectively).

	^{177}Lu-PNT2002 Arm	ARPI Arm
TEAEs of CTCAE Grade ≥3	30.1%	36.9%
Serious TEAEs	17.1%	23.1%
TEAEs Leading to Discontinuation	1.9%	6.2%

The open-label study randomized 412 patients with PSMA-expressing mCRPC who had progressed on ARPI therapy and either refused or were not eligible for chemotherapy, in a 2:1 randomization ratio (^{177}Lu-PNT2002: control group). At the time of the analysis, 84.6% of patients who experienced progressive disease in the control arm subsequently crossed over to receive ^{177}Lu-PNT2002. SPLASH was conducted across the United States, Canada, Europe, and the United Kingdom. Eighty percent of SPLASH patients resided in North America and approximately 10% of all participants were Black or African American.

"The success of ^{177}Lu-PNT2002 in this trial demonstrates the value of treating patients with radioligand therapy at this stage of the disease continuum. With only four treatment administrations over a 32-week period, this regimen provides reduced treatment intensity compared to the control arm, while also delaying disease progression with lower toxicity,” said Neil Fleshner, M.D., Co-founder and Chief Medical Officer at POINT Biopharma. “We extend our deepest gratitude to the SPLASH study participants and their families and caregivers, as well as the investigators and their hard-working staff."

“We are encouraged by the results of the SPLASH trial, which showed the benefits that ^{177}Lu-PNT2002 offers to patients with mCRPC. We are proud to be at the forefront of advancing the potential of targeted RLT with ^{177}Lu-PNT2002. As the leading radiopharmaceutical-focused company, we are committed to providing clinicians with cutting-edge options to fight disease and improve patient outcomes,” said Jean-Claude Provost, M.D., Chief Medical Officer at Lantheus. “We look forward to sharing additional data in the future, and to collaborating with regulatory authorities and POINT Biopharma to bring this promising therapy to the prostate cancer patient community.”

Full SPLASH trial results will be presented at a future medical congress.

About the SPLASH Trial

The phase 3 SPLASH trial is a multicenter, randomized, open label assessment of ^{177}Lu-PNT2002 in patients with PSMA-expressing mCRPC who have progressed on ARPI therapy and refuse, or are not eligible for, chemotherapy. The randomization phase of the study randomized 412 patients across North America, Europe, and the United Kingdom. Patients were randomized 2:1 with those in arm A receiving ^{177}Lu-PNT2002 and those in arm B receiving either abiraterone or enzalutamide. Patients in arm B who experience centrally assessed radiographic progression and meet protocol eligibility have the option to crossover and receive ^{177}Lu-PNT2002. Patients will be followed for up to 5 years from their first ^{177}Lu-PNT2002 dose. The primary endpoint of the study is radiographic progression-free survival. More information about the trial is accessible at www.ClinicalTrials.gov, identifier NCT04647526.

About ^{177}Lu-PNT2002

^{177}Lu-PNT2002 is a PSMA-targeted, lutetium 177-based radioligand therapy candidate that combines a PSMA-targeted ligand, PSMA-I&T, with the beta-emitting radioisotope no-carrier-added lutetium-177. Lantheus Holdings, Inc. in-licensed exclusive worldwide commercialization rights (excluding certain Asian territories) to ^{177}Lu-PNT2002 from POINT in December of 2022. In April of 2023, the FDA granted Fast Track designation for ^{177}Lu-PNT2002 for the treatment of 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.

About Prostate Cancer

Prostate cancer is the second most common form of cancer affecting men in the United States -- an estimated one in eight men will be diagnosed with prostate cancer in their lifetimes. The American Cancer Society estimates that in 2023, almost 288,300 new cases of prostate cancer will be diagnosed, and about 34,700 men will die of the disease.[1]

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.

About POINT Biopharma

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 oncology 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. 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” that are subject to risks and uncertainties. Forward-looking statements include, but are not limited to, statements relating to the potential of PNT2002 and statements regarding Lantheus’ and POINT’S expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Forward-looking statements may be identified by their use of terms such as "expected,” “look,” “planned,” “potential,” “will,” 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. Risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements include (i) the outcome of the SPLASH trial after full data is available; (ii) a delay in obtaining, or failure to obtain, a positive regulatory outcome from the FDA and regulatory authorities for PNT2002; (iii) the additional costs and risks associated with Lantheus’ ability to successfully launch PNT2002 as a commercial product; (iv) the market and patient receptivity to PNT2002 as a radiopharmaceutical therapy; (v) the existence, availability and profile of competing products and therapies; (vi) Lantheus’ ability to obtain and maintain adequate coding, coverage and payment for PNT2002; (vii) the intellectual property protection of PNT2002; (viii) POINT’s ability to successfully develop and scale the manufacturing capabilities to support the launch of PNT2002; and (ix) 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).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. Neither Lantheus nor POINT undertakes any 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.

Additional Information and Where to Find it

In connection with the proposed acquisition of POINT, Eli Lilly and Company (“Lilly”) caused its acquisition subsidiary to commence a tender offer for all of the issued and outstanding shares of common stock of POINT. This communication is for informational purposes only and is neither an offer to purchase nor a solicitation of an offer to sell any securities, nor is it a substitute for the tender offer materials that Lilly and its acquisition subsidiary filed with the SEC upon commencement of the tender offer. A solicitation and offer to buy outstanding shares of POINT is being made only pursuant to the tender offer materials that Lilly and its acquisition subsidiary have filed with the SEC. Lilly and its acquisition subsidiary have filed with the SEC a tender offer statement on Schedule TO, and POINT has filed a Solicitation/Recommendation Statement on Schedule 14D-9 with the SEC with respect to the tender offer. THE TENDER OFFER MATERIALS (INCLUDING AN OFFER TO PURCHASE, A RELATED LETTER OF TRANSMITTAL AND CERTAIN OTHER TENDER OFFER DOCUMENTS) AND THE SOLICITATION/RECOMMENDATION STATEMENT CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND THE PARTIES THERETO. INVESTORS AND STOCKHOLDERS OF POINT ARE URGED TO READ THESE DOCUMENTS CAREFULLY (AS EACH MAY BE AMENDED OR SUPPLEMENTED FROM TIME TO TIME) BECAUSE THEY CONTAIN IMPORTANT INFORMATION THAT INVESTORS AND STOCKHOLDERS OF POINT SHOULD CONSIDER BEFORE MAKING ANY DECISION REGARDING TENDERING THEIR SHARES OF COMMON STOCK IN THE TENDER OFFER. The tender offer materials (including the Offer to Purchase and the related Letter of Transmittal) are available to all stockholders of POINT at no expense to them at Lilly’s website at investor.lilly.com. The information contained in, or that can be accessed through, Lilly’s website is not a part of, or incorporated by reference in, this press release. The tender offer materials (including the Offer to Purchase and the related Letter of Transmittal), as well as the Solicitation/Recommendation Statement, are also available for free on the SEC’s website at www.sec.gov. In addition to the Offer to Purchase, the related Letter of Transmittal and certain other tender offer documents, as well as the Solicitation/Recommendation Statement, Lilly and POINT file annual, quarterly, and current reports, proxy statements and other information with the SEC. You may read any reports, statements or other information filed by Lilly and POINT with the SEC for free on the SEC’s website at www.sec.gov.

1. American Cancer Society. Facts & Figures 2023. American Cancer Society. Atlanta, GA. 2023

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