Lantheus Highlights Preliminary Study Results Demonstrating Potential of NM-01, a Novel Technetium-99m SPECT/CT Imaging Agent, to Assess PD-L1 Expression for Immunotherapy in Cancer

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Study Results Presented at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting

NORTH BILLERICA, Mass., June 13, 2022 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. ("the Company") (NASDAQ: LNTH) is committed to improving patient outcomes through diagnostics, radiotherapeutics and artificial intelligence solutions that enable clinicians to Find, Fight and Follow disease. Lantheus presented preliminary results of the PD-L1 Expression in Cancer (PECan) study at the Society of Nuclear Medicine and Molecular Imaging Annual Meeting. The results suggest that NM-01, a proprietary technetium 99m SPECT/CT imaging agent currently under development to assess PD-L1 expression in cancer cells, has the potential to identify patients who will respond to checkpoint inhibitor therapies and monitor early response in non-small cell lung cancer (NSCLC) pending further and ongoing investigation.

In the preliminary analysis, investigators were able to evidence intertumoral heterogeneity of PD-L1 expression between primary tumors and metastases. Further, baseline NM-01 SPECT/CT imaging was able to predict early metabolic 18F-FDG PET/CT response to anti-PD-L1 therapy in primary and metastatic tumors. Following therapy, PD-L1 expression measured by NM-01 SPECT/CT imaging demonstrated stability or a reduction in the majority of responding lesions.

"Immune checkpoint inhibition with PD-1 or PD-L1 alone or in combination with chemotherapy is a standard of care in the management of NSCLC. However, the methods currently used to measure PD-L1 expression, based on immunohistochemistry (IHC) assessment of biopsied tissue samples, are often suboptimal, making it difficult to select which patients will respond to therapy. The PECan study sets out to assess the relationship between PD-L1 expression as measured by NM-01 and metabolic response to anti-PD-L1 therapy in NSCLC," said Gary Cook, MD, King's College London, and principal investigator of the study. "Based on these initial findings, we are encouraged that NM-01 may play a role in identifying positive patient response to immune checkpoint inhibitor therapy."

The PECan study (NCT04436406) is planned to enroll 15 advanced NSCLC and 15 melanoma patients. The presentation reported the results of the first 10 NSCLC patients (median age: 64; 6 male, 4 female). Thoracic NM-01 SPECT/CT imaging was performed at two hours post injection of NM-01 before and after 9-weeks of an immunotherapy, anti-PD-1 pembrolizumab, alone or in combination with chemotherapy. Tumor to blood pool ratio (T:BP) measurements were performed in primary and metastatic lesions. Intertumoral heterogeneity of PD-L1 expression, defined as ≥50% difference in T:BP between primary and individual metastatic sites, was measured on NM-01 SPECT/CT at baseline. IHC was performed using the Ventana PD-L1 SP263 assay. The primary objective with respect to NSCLC is to determine the percentage change in PD-L1 expression between baseline and 9-week NM-01 SPECT/CT in patients receiving treatment. The relationship of baseline PD-L1 expression measured by NM-01 SPECT/CT and PD-L1 expression determined by IHC is also being measured.

Intertumoral heterogeneity of PD-L1 expression measured on baseline NM-01 SPECT/CT was present in 6 of 10 patients. Response to treatment as assessed by change in 18F-FDG-PET/CT at 9-weeks (n=7) correlated with high baseline PD-L1 expression measured by NM-01 T:BP (r=-0.71, p=0.037), but not with IHC results (r=0.003, p=0.498). Primary tumor baseline NM-01 T:BP ≥4.0 predicted 9-week metabolic response with 100% sensitivity and specificity. Metastasis NM-01 T:BP ≥2.65 predicted metabolic response with 72% sensitivity and 100% specificity. A majority (89%) of the primary or metastatic lesions that showed metabolic response were associated with stable or decreased PD-L1 expression by NM-01.

The study is ongoing and final results will be presented at a future date.

"These results provide important insights which may ultimately improve patient outcomes in NSCLC. Assessment of PD-L1 expression is currently performed on tumor biopsy samples using immunohistochemistry and discrepancies in checkpoint inhibitor treatment response have highlighted potential deficiencies in this method. Further, immunohistochemical assessment of tumor samples obtained by needle biopsy is highly invasive and often unable to capture the heterogeneity and dynamic nature of PD-L1 expression within the tumor and its microenvironment," explained Jean-Claude Provost, MD, Interim Chief Medical Officer, Lantheus. "We believe NM-01 could address these unmet clinical needs, by providing an alternative to biopsies with whole-body PD-L1 imaging assessment in a single examination. We are excited to explore its use before, during and after treatment with checkpoint inhibitors and in immune-oncology clinical trials to potentially improve patient selection and monitor response to therapy."

About Lantheus

With more than 60 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.

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 "believe," "currently," "explore," "future," "may," "ongoing," "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. 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 the PECan study, evaluating the use of NM-01 to assess PD-L1 expression in cancer cells, identify patients who will respond to checkpoint inhibitor therapies and monitor early response in non-small cell lung cancer; (ii) our ability to develop NM-01 as a SPECT/CT imaging agent; and (iii) the risks and uncertainties discussed in our filings with the Securities and Exchange Commission (including those described in the Risk Factors section in our Annual Reports on Form 10-K and our Quarterly Reports on Form 10-Q).

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