Lantheus Announces First Patient Dosed in Phase 2 Clinical Trial of NM-01 to Monitor PD-L1 Expression in Non-Small Cell Lung Cancer (NSCLC) Patients

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NM-01 is a novel technetium-99m SPECT imaging agent currently being developed for the assessment of PD-L1 expression in cancer cells

NORTH BILLERICA, Mass., May 13, 2022 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. ("the Company") (NASDAQ: LNTH), an established leader and fully integrated provider committed to innovative imaging diagnostics, targeted therapeutics and artificial intelligence solutions to Find, Fight and Follow serious medical conditions, today announced the first patient has been dosed in a Phase 2 trial evaluating NM-01, its proprietary technetium 99m SPECT imaging agent used to assess PD-L1 expression in cancer cells, for its potential to identify patients who will respond to checkpoint inhibitor therapies.

The PELICAN trial (NCT04992715) is an open-label, single-arm trial in non-small cell lung cancer (NSCLC) patients. The primary endpoint is the assessment of PD-L1 expression in primary tumor and metastatic lesions by NM-01 compared to immunohistochemistry. Other objectives will look at quantifying intra- and inter-tumoral heterogeneity of PD-L1 expression by NM-01, as well as establishing correlation with other diagnostic procedures. The trial is being conducted by Lantheus' partner NanoMab Technology Limited (NanoMab) at King's College London. Lantheus licensed NM-01 from NanoMab in 2019.

"While checkpoint inhibitor therapies targeting PD1 or PD-L1 have improved the prognosis for NSCLC patients, there are often unpredictable outcomes with these therapies for patients," said Gary Cook, MD, King's College London, and principal investigator of the trial. "PELICAN will help us determine if NM-01 can aid in selecting responders to checkpoint inhibitor therapies, thereby getting the right treatments to the right patients while sparing non-responders from unnecessary side-effects, procedures and costs."

Current assessment of PD-L1 expression is performed on tumor biopsy samples using immunohistochemistry. Discrepancies in checkpoint inhibitor treatment response have highlighted potential deficiencies in the current method of evaluating PD-L1 expression in a clinical setting. Immunohistochemical assessment of tumor samples obtained by needle biopsy is often unable to capture the heterogeneity and dynamic nature of PD-L1 expression within the tumor and its microenvironment. NM-01, an imaging agent targeting PD-L1 receptors, can provide whole-body imaging assessment in a single examination and could overcome these issues and represent an alternative to multiple biopsies. NM-01 potentially allows detection of PD-L1 expression in tumors and could be used in the management of patients before, during, or after treatment with checkpoint inhibitors. NM-01 could also be used in immune-oncology clinical trials to improve patient selection and monitor response to therapy.

"The future potential for targeted imaging agents, like NM-01, to inform clinical decision-making in oncology is very exciting," said Jean-Claude Provost, MD, Interim Chief Medical Officer, Lantheus. "We are pleased to take this important step forward in the development of a novel imaging agent that is designed to provide new information to optimize the use of checkpoint inhibitor therapies, improve patient outcomes and limit the need for multiple biopsies to be performed over the course of checkpoint inhibitor treatment."

"This is an important step forward in our development of NM-01 as a non-invasive in vivo imaging and patient selection tool for immune checkpoint drugs," said Dr. Hong Hoi Ting, co-founder and CSO, NanoMab. "We are excited about the potential to address an unmet clinical need in oncology, and know that Lantheus, a leader in the development and commercialization of imaging agents, is the right partner for this program."

About Lantheus Holdings, Inc.
Lantheus Holdings, Inc. is the parent company of Lantheus Medical Imaging, Inc., Progenics Pharmaceuticals, Inc. and EXINI Diagnostics AB and an established leader and fully integrated provider committed to innovative imaging diagnostics, targeted therapeutics and artificial intelligence solutions to Find Fight and Follow® serious medical conditions. Lantheus provides a broad portfolio of products, including the echocardiography agent DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension; PYLARIFY®, a PSMA PET imaging agent for the detection of suspected recurrent or metastatic prostate cancer; PYLARIFY AI™, an artificial intelligence platform that assists in the evaluation of PSMA PET images; TechneLite® (Technetium Tc99m Generator), a technetium-based generator that provides the essential medical isotope used in nuclear medicine procedures; AZEDRA® for the treatment of certain rare neuroendocrine tumors; and RELISTOR® for the treatment of opioid-induced constipation, which is partnered with Bausch Health Companies, Inc. The Company is headquartered in North Billerica, Massachusetts with 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 “can,” “continue,” “could,” “future,” “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 PELICAN, evaluating the use of NM-01 to assess PD-L1 expression in cancer cells; (ii) our ability to develop NM-01 as a SPECT 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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