Lantheus Holdings Announces Submission of Drug Master File for NM-01 in the U.S.

January 12, 2021

NORTH BILLERICA, Mass.--(BUSINESS WIRE)--Jan. 12, 2021-- Lantheus Holdings, Inc. (NASDAQ: LNTH) (Lantheus), the parent company of Lantheus Medical Imaging, Inc. and Progenics Pharmaceuticals, Inc., and a global leader in the development, manufacture and commercialization of innovative diagnostic and therapeutic agents and products, announced that it has filed a Drug Master File (DMF) with the U.S. Food and Drug Administration (FDA) for NM-01, a PD-L1 imaging biomarker, and will begin making the biomarker available to academic centers and pharmaceutical companies for use in immuno-oncology (I/O) clinical trials in 2021.

NM-01 is a proprietary radiopharmaceutical biomarker using a camelid single-domain antibody and a technetium-99 radioisotope that has demonstrated a high affinity for PD-L1 protein. NM-01 could provide a specific, non-invasive approach to patient assessment, including use in whole-body imaging, or virtual biopsy. NM-01 potentially allows detection of PD-L1 expression in tumors and could be used to evaluate patients before, during, or after treatment with I/O agents, including checkpoint inhibitors, in clinical trials. The market for checkpoint inhibitors is expected to grow from $25B in 2019 to $68B in 2026.[1] Lantheus licensed NM-01 from NanoMab Technology Limited in 2019 and plans to provide NM-01 as a clinical research tool, together with support and analytics, to pharmaceutical companies and the largest academic centers conducting clinical research in I/O.

“Evaluation of patients for I/O therapy is a key challenge for companies developing new therapeutics in this high-growth field,” said Etienne Montagut, Senior Vice President of Corporate Development at Lantheus. “With the filing of the DMF, Lantheus is pleased to take an important step forward in providing a novel clinical research tool with the potential to provide new information to optimize the use of I/O therapy.”

NanoMab has completed a Phase 1 study using NM-01 in 30 non-small cell lung cancer (NSCLC) patients, and preliminary data of the first 16 patients were published in the February 22, 2019 issue of Journal of Nuclear Medicine (Xing et al.). Separately, an investigator-led clinical trial involving 30 patients with either NSCLC or melanoma is in progress at King’s College London and Guy’s and St Thomas’ NHS Trust (NCT04436406); the study aims to monitor treatment response. A clinical trial authorization (CTA) was also granted by the Medicines Healthcare Products Regulatory Agency (MHRA) in November 2020 for a Phase 2 clinical study on NM-01 in NSCLC patients.

“We are very encouraged by the results of the Phase I study, which validated our innovative nanobody platform and demonstrated strong correlation with tissue-based biomarker,” said Dr. H.H. Ting, Chief Executive Officer of NanoMab. “We are pleased that leading cancer research centers are progressing with the use of NM-01 in I/O clinical trials.”

About a Drug Master File (DMF)

A Drug Master File (DMF) is a submission to the Food and Drug Administration that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.[2]

About NanoMab Technology Limited

NanoMab Technology Limited is a privately held biopharmaceutical company focusing on cancer precision therapies via the development of radiopharmaceuticals. The company’s goal is to develop a pipeline of theranostics with its proprietary camelid antibody platform to address the unmet medical need for cancer patients across the world. An IMPD on NM-01 was filed with UK Medical Healthcare products Regulatory Agency (MHRA) last year. NanoMab is also developing its radio-labelled NM-02 for clinical trials in both imaging and treatment of breast and gastric cancers. NanoMab’s third program, NM-03, a single domain antibody targeting a pan-cancer marker, is in preclinical development as a theranostic. NanoMab is registered in Hong Kong with offices in London and Shanghai (www.nano-mab.com).

About Lantheus Holdings, Inc.

Lantheus Holdings, Inc. is the parent company of Lantheus Medical Imaging, Inc. and Progenics Pharmaceuticals, Inc., and a global leader in the development, manufacture and commercialization of innovative diagnostic and therapeutic agents and products. Lantheus provides a broad portfolio of products, including the echocardiography agent DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension; 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 York, New Jersey, Puerto Rico, 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 “anticipate,” “believe,” “confident,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “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) pharmaceutical company and academic center receptivity to NM-01 as a clinical research tool; (ii) the safety and efficacy of NM-01; (iii) regulatory risks related to NM-01; (iv) our dependence upon third parties for the manufacture and supply of NM-01; (v) expectations for future clinical trials, the timing and potential outcomes of clinical studies and filings and other interactions with regulatory authorities; (vi) the impact of legislative, regulatory, competitive and technological changes; and (vii) the risk 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).

[1]GlobalData Consensus Forecasts Accessed 01-11-2021 using the criteria immuno-oncology and targets PD-1, PDL-1 and CTLA-4
[2]Drug Master File Guidelines. Accessed at https://www.fda.gov/drugs/guidances-drugs/drug-master-files-guidelines

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Source: Lantheus Holdings, Inc.