Lantheus Holdings Announces FDA Clearance for AI-Enabled Automated Bone Scan Index (aBSI) in Prostate Cancer on GE Healthcare's Xeleris Platform

Nov 13, 2020

NORTH BILLERICA, Mass.--(BUSINESS WIRE)--Nov. 13, 2020-- Lantheus Holdings, Inc. (the "Company") (NASDAQ: LNTH), the parent company of Lantheus Medical Imaging, Inc., Progenics Pharmaceuticals, Inc., and EXINI Diagnostics AB, and a global leader in the development, manufacture and commercialization of innovative diagnostic and therapeutic agents and products, announced the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for the use of Lantheus' artificial intelligence enabled automated bone scan index (aBSI) product on GE Healthcare's Xeleris platform.

"Lantheus is delighted by the U.S. approval of our digital AI solution for prostate cancer, aBSI, on GE Healthcare's platform. As a leading multinational medical technology company with deep experience in medical imaging and diagnostics, GE Healthcare presents the ideal attributes to provide global access to this unique digital solution," said Etienne Montagut, Sr. Vice President of Corporate Development. "aBSI has demonstrated clinical value in quantifying and managing disease progression in advanced prostate cancer patients with the potential to support critical clinical decisions. Lantheus will continue to develop AI solutions to augment and expand the utility of imaging diagnostics for precision medicine in oncology," Mr. Montagut added.

In October 2019, the Company entered into a global software licensing agreement with GE Healthcare for the rights to aBSI, a vendor neutral stand-alone platform that is enabled with artificial intelligence, which has been trained to automate the detection of hotspots in bone indicative of metastatic disease and calculate the aBSI. The platform offers a fast and reliable alternative to manual interpretation of bone scan images of metastatic prostate cancer. Recent investigations have demonstrated the clinical utility of aBSI as a prognostic and a response imaging biomarker in patients with metastatic prostate cancer.[1,2]

"The pandemic has proven that data, analytics, AI and connectivity will only become more central to delivering care," said Erez Levy, General Manager, Nuclear Medicine, GE Healthcare. "For GE Healthcare, that means continuing to advance intelligent and innovative technologies, like aBSI, and deliver precision health to promote better patient outcomes around the world."

Under the terms of the non-exclusive agreement, GE Healthcare acquired from Lantheus the software license for aBSI for integration into GE Healthcare's Xeleris platform, excluding the use of aBSI in Japan. Under the agreement with GE Healthcare, Lantheus will receive tiered licensing fees per license sold.

About aBSI

The aBSI product is vendor neutral stand-alone software as a medical device which calculates the automated bone scan index in Technetium-99m bone scintigraphy. aBSI received FDA clearance in 2019 (K191262). The product is enabled with a neural network that has been trained to automate the detection of hotspots and calculate the aBSI value.

About Lantheus Holdings, Inc.

Lantheus Holdings, Inc. is the parent company of Lantheus Medical Imaging, Inc., Progenics Pharmaceuticals, Inc., and EXINI Diagnostics AB, 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.

About GE Healthcare

GE Healthcare is the $16.7 billion healthcare business of GE (NYSE: GE). As a leading global medical technology and digital solutions innovator, GE Healthcare enables clinicians to make faster, more informed decisions through intelligent devices, data analytics, applications and services, supported by its Edison intelligence platform. With over 100 years of healthcare industry experience and around 50,000 employees globally, the company operates at the center of an ecosystem working toward precision health, digitizing healthcare, helping drive productivity and improve outcomes for patients, providers, health systems and researchers around the world.

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) the market receptivity to aBSI and to GEHC’s XELERIS platform; (ii) the intellectual property protection of aBSI; and (iii) 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).

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[1] Armstrong AJ, Anand A, Edenbrandt L,et al. Phase 3 Assessment of the Automated Bone Scan Index as a Prognostic Imaging Biomarker of Overall Survival in Men With Metastatic Castration-Resistant Prostate Cancer: A Secondary Analysis of a Randomized Clinical Trial. JAMA Oncol. 2018 Jul 1;4(7):944-951.

[2] Ali A, Hoyle AP, Parker CC, et al. The Automated Bone Scan Index as a Predictor of Response to Prostate Radiotherapy in Men with Newly Diagnosed Metastatic Prostate Cancer: An Exploratory Analysis of STAMPEDE’s “M1|RT Comparison”. European Urology. 2020 Aug; 3(4): 412-419

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