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European Commission Approves Navidea's Sentinel Lymph Node Detection Agent Lymphoseek®

Approval Sets the Stage for Revenue Generation through Targeted Launches in Europe

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAV) has announced that the European Commission has granted marketing authorization for Lymphoseek® 250 micrograms kit for radiopharmaceutical preparation. Lymphoseek is now approved in the European Union (EU) for use in imaging and intraoperative detection of sentinel lymph nodes draining a primary tumor in adult patients with breast cancer, melanoma, or localized squamous cell carcinoma of the oral cavity.

"This is yet another important milestone achieved by Navidea in our global commercialization of Lymphoseek and reaffirms our commitment to improving the lives of oncology patients worldwide," said Navidea CEO, Rick Gonzalez. "We are excited that Lymphoseek is the first agent centrally approved in Europe for Sentinel Lymph Node (SLN) detection. It is differentiated in its ability to reliably and accurately locate SLNs to effectively stage cancer and inform post-surgical treatment. We look forward to making Lymphoseek available throughout Europe with initial launches into certain major markets planned for later in 2015. We will be sharing more details about our commercialization plans in the coming months."

"Lymphoseek can be a game changer in allowing more patients across Europe access to this technology which allows their cancer to be accurately staged without disfiguring and disabling surgery," said John Buscombe, Physician in Nuclear Medicine, Addenbrooke's Hospital, Cambridge, UK. "The availability and convenience of a receptor-targeted imaging agent such as Lymphoseek, the first synthetic and biotargeted agent for use in sentinel node localization, provides both the required diagnostic accuracy and reliability that enables a surgeon planning sentinel node biopsy to be able to operate without the concerns raised with timing from imaging to surgery found with alternate methods."

The sentinel node detection label in Europe may now allow Lymphoseek to be used in approximately 367,000, 83,000 and 55,000 new cases of breast cancer, melanoma and oral cavity cancers diagnosed in Europe annually, respectively.

Lymphoseek is approved in the U.S. for use in lymphatic mapping to locate lymph nodes draining a primary tumor site in patients with solid tumors for which this procedure is a component of intraoperative management and for guiding Sentinel Lymph Node Biopsy (SLNB) using a handheld gamma counter in patients with node negative squamous cell carcinoma of the oral cavity, breast cancer or melanoma.

About Lymphoseek

Lymphoseek® (technetium Tc 99m tilmanocept) injection is the first and only FDA-approved receptor-targeted lymphatic mapping agent. It is a novel, receptor-targeted, small-molecule radiopharmaceutical used in the evaluation of lymphatic basins that may have cancer involvement in patients. Lymphoseek is designed for the precise identification of lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. Lymphoseek is approved by the U.S. Food and Drug Administration (FDA) for use in solid tumor cancers where lymphatic mapping is a component of surgical management and for guiding sentinel lymph node biopsy in patients with clinically node negative breast cancer, melanoma or squamous cell carcinoma of the oral cavity. Lymphoseek has also received European approval in imaging and intraoperative detection of sentinel lymph nodes in patients with melanoma, breast cancer or localized squamous cell carcinoma of the oral cavity.

Accurate diagnostic evaluation of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. Overall in the U.S., solid tumor cancers may represent up to 1.2 million cases per year. The sentinel node label in the U.S. and Europe may address approximately 235,000 new cases of breast cancer, 76,000 new cases of melanoma and 45,000 new cases of head and neck/oral cancer in the U.S., and approximately 367,000 new cases of breast cancer, 83,000 new cases of melanoma and 55,000 new cases of head and neck/oral cancer diagnosed in Europe annually.

EU Lymphoseek® Indication and Important Safety Information

Radiolabelled Lymphoseek is indicated for imaging and intraoperative detection of sentinel lymph nodes draining a primary tumour in adult patients with breast cancer, melanoma, or localised squamous cell carcinoma of the oral cavity.

External imaging and intraoperative evaluation may be performed using a gamma detection device.

Important Safety Information about Lymphoseek for EU patients

In clinical trials with Lymphoseek, no serious hypersensitivity reactions were reported, however Lymphoseek may pose a risk of such reactions due to its chemical similarity to dextran. Serious hypersensitivity reactions have been associated with dextran and modified forms of dextran (such as iron dextran drugs).

Prior to the administration of Lymphoseek, patients should be asked about previous hypersensitivity reactions to drugs, in particular dextran and modified forms of dextran. Resuscitation equipment and trained personnel should be available at the time of Lymphoseek administration, and patients observed for signs or symptoms of hypersensitivity following injection.

Any radiation-emitting product may increase the risk for cancer. Adhere to dose recommendations and ensure safe handling to minimize the risk for excessive radiation exposure to patients or health care workers.

In clinical trials, no patients experienced serious adverse reactions and the most common

adverse reactions were injection site irritation and/or pain (<1%).

Prescribing information and more information about Lymphoseek for EU patients will be available at: http://ec.europa.eu/health/documents/community-register/index_en.htm

For full prescribing information and more information about Lymphoseek for U.S. patients, please visit: www.lymphoseek.com

About Navidea Biopharmaceuticals Inc.

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. Navidea is developing multiple precision diagnostic products and platforms including Manocept™, NAV4694, NAV5001, and NAV1800 (RIGScan™), to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and, ultimately, patient care. Lymphoseek® (technetium Tc 99m tilmanocept) injection, Navidea's first commercial product from the Manocept platform, was approved by the FDA in March 2013 and by the EMA in November 2014. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel radiopharmaceutical agents and advancing the Company's pipeline through selective acquisitions, global partnering and commercialization efforts. For more information, please visit www.navidea.com.

The Private Securities Litigation Reform Act of 1995 (the Act) provides a safe harbor for forward-looking statements made by or on behalf of the Company. Statements in this news release, which relate to other than strictly historical facts, such as statements about the Company's plans and strategies, expectations for future financial performance, new and existing products and technologies, anticipated clinical and regulatory pathways, and markets for the Company's products are forward-looking statements within the meaning of the Act. The words "believe," "expect," "anticipate," "estimate," "project," and similar expressions identify forward-looking statements that speak only as of the date hereof. Investors are cautioned that such statements involve risks and uncertainties that could cause actual results to differ materially from historical or anticipated results due to many factors including, but not limited to, the Company's continuing operating losses, uncertainty of market acceptance of its products, reliance on third party manufacturers, accumulated deficit, future capital needs, uncertainty of capital funding, dependence on limited product line and distribution channels, competition, limited marketing and manufacturing experience, risks of development of new products, regulatory risks and other risks detailed in the Company's most recent Annual Report on Form 10-K and other Securities and Exchange Commission filings. The Company undertakes no obligation to publicly update or revise any forward-looking statements.

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