

December 19, 2013



European Medicines Agency (EMA) Continues Marketing Authorization Application (MAA) Review for Lymphoseek®

- Global market development activities remain on target -

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, announced today that the European Medicines Agency (EMA) has provided updated Day 180 feedback and has elected to continue the assessment of the Marketing Authorization Application (MAA) for Lymphoseek® (technetium 99m tilmanocept) Injection. The updated Day 180 feedback was limited to supplemental product specification data and the NEO3-06 Phase 3 study in Head and Neck Cancer, which was submitted later in the MAA review process at Day 120, leaving less time for evaluation of these new data. The MAA review clock will continue to be stopped at Day 180 to await Navidea's responses to the updated EMA feedback. During this time, the MAA remains active and Navidea will continue its ongoing process of interacting with the EMA.

"With the Lymphoseek MAA remaining in the EMA's assessment process, we will continue to work with the EMA to support a positive opinion as early as possible in 2014," stated Mark Pykett, VMD, PhD, Navidea CEO. "We view potentially gaining a positive opinion that would also include Head and Neck Cancer as advantageous. While we prepare our responses to the EMA's updated Day 180 feedback, we will continue to implement our plans for European market development during 2014 which we believe will support material revenue generation from Europe beginning in 2015, as we have previously disclosed."

Expanding Global Efforts

Navidea's activities in Europe are part of its expanding global strategy for Lymphoseek commercialization. The Company recently announced it has entered into a partnership agreement for Lymphoseek distribution in Canada; partnerships are in process for additional markets. Navidea has also commenced shipment of Lymphoseek to select medical centers in the Middle East. These market expansion activities build on the growth of Lymphoseek sales being seen in the United States, which continue the positive trends recently reported at the Company's Analyst Science Day on December 5, 2013.

About Lymphoseek®

Lymphoseek® (technetium Tc 99m tilmanocept) Injection is a novel, receptor-targeted, small-molecule radiopharmaceutical used in lymphatic mapping procedures that are performed to help in the diagnostic evaluation of potential cancer spread for patients with breast cancer and melanoma. Lymphoseek is designed to identify the lymph nodes that

drain from a primary tumor, which have the highest probability of harboring cancer. Lymphoseek was approved by the U.S. Food and Drug Administration in March, 2013 for use in lymphatic mapping to assist in the localization of lymph nodes draining a primary tumor in patients with breast cancer or melanoma. The Company anticipates continuing development of Lymphoseek into other solid tumor areas that may include head and neck cancers, prostate cancer, thyroid cancer, lung/bronchus cancers, colorectal cancer and others. Lymphoseek was granted Fast Track designation in December 2013 for sentinel lymph node detection in patients with head and neck cancer.

Accurate diagnostic evaluation of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. According to publicly available information, approximately 232,000 new cases of breast cancer, 77,000 new cases of melanoma and 67,000 new cases of head and neck/oral cancer are expected to be diagnosed in the United States in 2013, with approximately 330,000 new cases of breast cancer, 69,000 new cases of melanoma and 95,000 new cases of head and neck/oral cancer diagnosed in Europe annually.

U.S. Indication and Important Safety Information About Lymphoseek

Indication

Lymphoseek (technetium Tc 99m tilmanocept) Injection is a lymphatic mapping agent indicated for use with a hand-held gamma counter to assist in the localization of lymph nodes draining a primary tumor site in patients with breast cancer or melanoma.

Important Safety Information

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.

The most common adverse reactions are injection site irritation and/or pain (<1%).

FULL LYMPHOSEEK PRESCRIBING INFORMATION CAN BE FOUND AT:

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 NAV4694, NAV5001, Manocept™ and 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 99m tilmanocept) Injection, Navidea's first commercial product from the Manocept platform, was approved by the FDA in March 2013. 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.

Navidea Biopharmaceuticals
Brent Larson, 614-822-2330
Executive VP & CFO
or
Sharon Correia, 978-655-2686
Associate Director, Corporate Communications

Source: Navidea Biopharmaceuticals, Inc.