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Navidea Biopharmaceuticals Provides Update on European Marketing Authorization Application for Lymphoseek®

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, announced that today it held an update meeting with the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for the pending Marketing Authorization Application (MAA) of Lymphoseek® (technetium Tc 99m tilmanocept) Injection. Lymphoseek is a lymphatic mapping agent designed to identify the lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. As part of the MAA review process, Navidea presented Oral Explanations to the CHMP relating to open questions in the Lymphoseek MAA. At the conclusion of the meeting, the CHMP informed Navidea that the Committee will continue with its review of the MAA. Navidea believes the course of the review continues to be supportive of its market development plans and outlook for material revenue generation in Europe beginning in 2015, as previously disclosed.

Based on feedback received at the meeting, Navidea believes that the CHMP has found the safety and efficacy data submitted in the MAA for breast cancer and melanoma to be acceptable. The CHMP will now focus its review on the remaining areas of product specifications unique to the European application and on data from the Phase 3 study in head and neck cancer. During this process, the MAA remains active but the review clock will continue to be stopped while Navidea works with the CHMP to address these remaining areas.

"The European review of Lymphoseek continues to progress. The Oral Explanation meeting was productive and provided an opportunity for both Navidea and our technical experts to discuss the Lymphoseek application with the CHMP. We achieved our goals in this meeting of getting positive feedback on the breast cancer and melanoma aspects of the filing and clarifying the remaining areas of focus so the review can proceed in a timely manner. We appreciate the CHMP's constructive input and guidance," stated Mark Pykett, VMD, PhD, Navidea CEO. "We will continue our ongoing dialogue with the EMA to address remaining areas and plan to provide further updates on this process in the coming weeks."

The Lymphoseek MAA is supported by a comprehensive, multi-trial clinical program including two Phase 3 studies of Lymphoseek (NEO3-05 and NEO3-09) performed in patients with either breast cancer or melanoma and a third Phase 3 study (NEO3-06), in patients with head and neck cancer, contributing to a safety database of more than 550 patients. The MAA is based on the same pivotal efficacy and safety data package provided

in the U.S. New Drug Application (NDA) and two supplemental NDA (sNDA) submissions. The U.S. Food and Drug Administration (FDA) approved Lymphoseek in the United States in 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. Lymphoseek was also granted Fast Track designation and Priority Review for one of its sNDAs focused on sentinel lymph node detection in patients with head and neck cancer, with an upcoming Prescription Drug User Fee Act (PDUFA) target date of June 16, 2014. The second sNDA has a PDUFA target date of October 16, 2014.

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 (FDA) 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 and Priority Review designation for its sNDA for sentinel lymph node detection in patients with head and neck cancer and is currently in review with the FDA.

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 235,000 new cases of breast cancer, 76,000 new cases of melanoma and 69,500 new cases of head and neck/oral cancer are expected to be diagnosed in the United States in 2014, and approximately 367,000 new cases of breast cancer, 83,000 new cases of melanoma and 137,000 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 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. 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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