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Navidea Announces Acceptance for Review of an Additional sNDA to Further Expand Lymphoseek® Labeling

- Additional Supplemental New Drug Application (sNDA) for Lymphoseek focuses on more flexible and expanded utilization practices -

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, announced today that the U.S. Food and Drug Administration (FDA) has accepted for review an additional Supplemental New Drug Application (sNDA) for the proposed expanded label for Lymphoseek® (technetium 99m tilmanocept) Injection to support broader and more flexible use in imaging and lymphatic mapping procedures, including lymphoscintigraphy and other optimization capabilities. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target review date for the second Lymphoseek sNDA of October 16, 2014.

The two Lymphoseek sNDAs now accepted are derived from a single, data-rich application submitted to FDA in December 2013. In assessing the application, FDA chose to separate the filing in two based on the proposed labeling extensions requested and the scope of information provided. This second sNDA application is aimed at expanding the Lymphoseek label to support more flexible utilization practices for Lymphoseek in lymphatic mapping and lymphoscintigraphy imaging. The first sNDA, aimed at Lymphoseek's use as a sentinel lymph node detection agent in patients with head and neck cancer, received FDA Fast Track designation and was accepted for Priority Review, as previously announced, with a PDUFA date target of June 16, 2014. Lymphoseek is currently approved for use in lymphatic mapping procedures performed to aid in the diagnostic evaluation of lymph nodes draining a primary tumor in patients with breast cancer and melanoma.

"The FDA's decision to review an additional sNDA to further expand Lymphoseek's labeling underscores our belief that the agent can make a critical difference for patients as part of their overall diagnosis and treatment," commented Cornelia Reininger, MD, PhD, Navidea's Senior Vice President and Chief Medical Officer. "Additionally, the FDA's decision to grant Priority Review for our first Lymphoseek sNDA focused on sentinel lymph node (SLN) detection in patients with head and neck cancer supports recognition that Lymphoseek-guided SLN detection in this disease can have a significant impact on morbidity. Label expansion for these sNDAs, if approved, may allow for broader cancer-type use, enable more consistent and standardized lymphatic mapping and lymphoscintigraphy analysis, and address important areas of unmet medical need."

The second Lymphoseek sNDA seeks to expand product claims to enable broader and more flexible utilization of the agent in routine practice, including lymphoscintigraphy imaging and flexible timing of Lymphoseek administration allowing for a 2-day protocol. Data submitted in

support of these parameters were derived from Navidea's series of prospective, well-controlled Phase 3 studies in patients with breast cancer, head and neck cancer, and melanoma. These study results demonstrated the ability of Lymphoseek to detect lymph nodes in same-day or subsequent-day surgery following injection, as well as being used in lymph node imaging, or lymphoscintigraphy.

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 and Priority Review designation for its sNDA 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 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 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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