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FDA Grants Fast Track Designation to Navidea Biopharmaceuticals' Lymphoseek® for Sentinel Lymph Node Detection in Patients with Head and Neck Cancer

– Fast-Track designation may expedite supplemental New Drug Application (sNDA) approval process –

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAV), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, announced today that the US Food and Drug Administration (FDA) has granted Fast Track designation to Lymphoseek® (technetium 99m tilmanocept) Injection for sentinel lymph node detection in patients with head and neck cancer. Under the FDA Modernization Act of 1997, the Fast Track program was designed to facilitate the development and expedite the review of drug candidates intended to treat serious or life-threatening conditions, and that demonstrate the potential to address unmet medical needs. Navidea intends to file the supplemental New Drug Application (sNDA) for Lymphoseek before year-end. Lymphoseek was approved by the FDA in March 2013 for use in lymphatic mapping procedures that are performed to help in the diagnostic evaluation of potential cancer spread for patients with breast cancer and melanoma.

"The Fast Track designation Navidea has received for Lymphoseek recognizes the significant unmet need that exists in the treatment of head and neck cancers and the important role that Lymphoseek can play in reducing or eliminating the need for debilitating elective neck dissection surgery," said William J Regan, Navidea Senior Vice President for Global Regulatory Strategy. "After filing the sNDA, we look forward to working closely with the FDA to bring to market as quickly as possible an expanded label for Lymphoseek and what will be the first agent indicated in sentinel lymph node detection."

Lymphoseek NEO3-06 Clinical Trial Results

Navidea's Phase 3 clinical trial (NEO3-06) of Lymphoseek was a prospective, open-label, multicenter, within-patient study of Lymphoseek® (technetium Tc 99m tilmanocept) Injection. It was designed to identify sentinel lymph nodes (SLNs) and determine the false negative rate (FNR) associated with Lymphoseek-identified SLNs relative to the pathological status of non-SLNs in head and neck and intraoral squamous cell carcinoma. The primary endpoint for the NEO3-06 trial was based on the number of subjects with pathology-positive lymph nodes (lymph nodes found to harbor cancer) following a multiple level lymph node dissection and required a minimum of 38 subjects whose lymph nodes contained pathology-confirmed

disease. Of the more than 80 subjects enrolled in the NEO3-06 trial, 39 subjects were determined to have pathology-positive lymph nodes. Results demonstrated that Lymphoseek correctly identified 38 of these 39 patients, for an overall False Negative Rate (FNR) of 2.56%. This was statistically significant ($p=0.0205$) against the statistical threshold for success. These findings indicate that Lymphoseek accurately identified SLNs in these trial subjects, and is likely to be predictive of overall node pathology status. FNR is the rate of occurrence of negative test results in subjects known to have the disease for which the individual is being tested. Moreover, multiple level nodal dissection of patients in the trial with cancer-positive lymph nodes led to an average removal of 38 lymph nodes per patient, whereas Lymphoseek on average led to the removal of approximately 4 lymph nodes, representing a substantial reduction in potential morbidity for patients with head and neck cancer undergoing single lymph node biopsy. The study also reported no differences were observed in the ability of Lymphoseek to detect SLNs between same-day or subsequent-day surgery following Lymphoseek injection, and also evaluated the use of Lymphoseek 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.

Accurate diagnostic evaluation of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. According to the American Cancer Society, 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.

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.

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