April 11, 2013

Navidea's Presentation of Top-Line Interim Analysis of Lymphoseek® Head and Neck Phase 3 Trial Selected for Investigator Award

- Data presented at the 2nd International Symposium on Thoracic and Upper Aerodigestive Malignancies -

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that a presentation of results from its Phase 3 clinical trial of Lymphoseek® (technetium 99m tilmanocept) Injection in patients with head and neck squamous cell carcinoma received the 1st Investigator Award at the 2nd International Symposium on Thoracic and Upper Aerodigestive Malignancies. The symposium was held April 4-6, 2013 in Athens, Greece. The presentation of recently announced top-line interim results for the Phase 3 Lymphoseek study and a summary of results from three of the study's highest-accruing clinical trial sites were made by Dr. Michael Blue, MD, Senior Medical Director of Navidea Biopharmaceuticals, one of the authors.

Poster Title:

The CD206-Targeted, Molecular Sentinel Node Mapping Agent Tc99m-Tilmanocept Accurately Stages Head/Neck Squamous Cell Carcinomas (HNSCC): Prospective Interim Analysis Results From a Phase-3 Multi-Institutional Study.

Authors:

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The results presented by Dr. Blue *et al* included a summary of the pre-planned statistical interim analysis of the primary endpoint on the entire study, as recently announced by Navidea. The primary endpoint for the NEO3-06 trial was based on the number of subjects with pathology-positive lymph nodes (that is, 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. Thirty-nine subjects were determined to have pathology-positive lymph nodes and were included in the interim analysis. Results from these 39 subjects demonstrated that Lymphoseek accurately identified 38, for an overall

False Negative Rate (FNR) of 2.56%.

In addition, the authors reviewed a preliminary evaluation of the NEO3-06 trial data from three of the highest-accruing clinical sites. A total of 50 subjects were evaluated from these sites; 21 had pathology-positive lymph nodes. Results indicated that Lymphoseek identified these pathology-positive lymph nodes in 21 out of 21 subjects for an FNR of 0%. The total patient population included subjects with tongue tumors, floor of mouth tumors and other intraoral head and neck tumors. The authors concluded: "^{99m}Tc-tilmanocept demonstrated that the SLN status was highly predictive and consistent with the status of the neck for clinical stage and tumor location." They also noted that "timing of ^{99m}Tc-tilmanocept injection resulted in no difference in regards to pathology findings," in study subjects who had same day surgery versus next day surgery.

Navidea's Phase 3 clinical trial (NEO3-06) is a prospective, open-label, multicenter, within-patient study of Lymphoseek® (technetium Tc 99m tilmanocept) Injection. It is 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 NEO3-06 study is a supplement to previously conducted Phase 3 trials of Lymphoseek in breast cancer and melanoma that were designed to establish Lymphoseek as an effective radiopharmaceutical agent for use in lymphatic mapping procedures to identify the lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. Those studies formed the basis of the NDA registration package upon which the U.S. Food and Drug Administration based its U.S. approval of Lymphoseek in March, 2013. Navidea is conducting the NEO3-06 clinical study to provide evidence of Lymphoseek performance in a third cancer type and to potentially expand its product label.

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

U.S. 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

Tc99m-Tilmanocept is branded as Lymphoseek in the U.S.

About Navidea

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. Navidea is actively developing four radiopharmaceutical agent platforms – Lymphoseek®, NAV4694, NAV5001 and RIGScan™ – to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and, ultimately, patient care. 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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