

Independent Investigators Report Lymphoseek® Results in JAMA Otolaryngology Head and Neck Surgery

- Publication Details Findings of Phase 3 Clinical Trial of Lymphoseek in Head and Neck Cancer at The Ohio State University -

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE:NAV), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, announced today that results from the Phase 3 clinical trial of Lymphoseek® (technetium Tc 99m tilmanocept) Injection in Head and Neck Cancer (NEO3-06) at The Ohio State University Comprehensive Cancer Center – James Cancer Hospital & Solove Research Institute were published in the current edition of the peer-reviewed journal, *JAMA Otolaryngology Head and Neck Surgery*, a publication of the American Medical Association.

The publication, *“Use of a Novel Receptor-Targeted (CD206) Radiotracer, 99m-Tc-Tilmanocept, and SPECT/CT for Sentinel Lymph Node Detection in Oral Cavity Squamous Cell Carcinoma: Initial Institutional Report in an Ongoing Phase 3 Study,”* describes the experience at one of the clinical trial sites that participated in NE03-06, a Phase 3 study designed to assess the potential utility of Lymphoseek as a sentinel lymph node mapping agent in patients with head and neck cancer.

“The results, published independently by this single clinical trial site in our larger Phase 3 NE03-06 study, corroborate data for the ability of Lymphoseek to identify sentinel lymph nodes in head and neck squamous cell carcinoma,” said Mark Pykett, VMD, PhD, CEO of Navidea. “As Navidea previously announced, Lymphoseek met the primary endpoint in the NE03-06 trial, where it correctly identified pathology-positive lymph nodes in 38 of 39 patients, demonstrating a statistically significant overall False Negative Rate of 2.56 percent. We look forward to additional presentations of the broader dataset from our NE03-06 Phase 3 clinical trial in the coming months. We have closed the study following a constructive FDA meeting and with the recommendation of the Data Safety Monitoring Committee. Based on the NE03-06 study results and data analysis, we are working to file an sNDA for Lymphoseek by year end.”

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.

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 actively developing four radiopharmaceutical agent platforms – Lymphoseek® (technetium 99m tilmanocept) Injection, 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 first commercial agent, Lymphoseek, 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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