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Navidea Biopharmaceuticals Announces Presentation of Meta-Analysis Results of Lymphoseek® and ACOSOG Radiolabeled Colloid in Head and Neck Cancer

Lymphoseek Demonstrated Statistically Significant Efficacy and Overall Accuracy Performance in Identification of Sentinel Lymph Nodes

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced results from a meta-analysis study of Lymphoseek® (technetium Tc 99m tilmanocept) Injection, a novel, receptor-targeted, small-molecule radiopharmaceutical. The study compared Lymphoseek performance data from a pre-planned interim analysis of its Phase 3 clinical trial (NEO3-06) versus published data from the ACOSOG Z-0360 trial which was done using radiolabeled sulfur colloid. Results in this study demonstrated that Lymphoseek identified sentinel lymph nodes (SLNs) in subjects with squamous cell carcinoma of the head or neck (SCC) with a False Negative Rate (FNR) of 2.56%, whereas sulfur colloid demonstrated an FNR of 10% (p=0.0006). Lymphoseek identified SLNs with an overall accuracy of 99%, versus an overall accuracy of sulfur colloid of 97%. Dr. Francisco J. Civantos, MD, FACS, University of Miami School of Medicine, Miami, Fla., presented the results in an oral presentation at the 2013 Annual Meeting of the Society of Nuclear Medicine and Molecular Imaging (SNMMI) in Vancouver, Canada.

“False negative rates and overall accuracy are key metrics used to define the potential for performance of radiolabeled agents in lymphatic mapping and the evaluation of nodal metastasis. We believe the fact that Lymphoseek achieved statistically significant results, with a false negative rate of only 2.56% and 99% overall accuracy, attests to the performance of the product in identifying the appropriate tumor-draining lymph nodes,” said Frederick O. Cope, PhD, Senior Vice President and Chief Scientific Officer at Navidea.

“The removal of minimal lymph tissue while obtaining appropriate information as to whether cancer has spread is one of the key goals of sentinel lymph node biopsy, because approximately 75% of head and neck cancer patients may have pathology-negative lymph nodes and therefore do not require surgical removal of the full regional lymph node chain, as is a typical practice currently,” commented Dr. Civantos. “New receptor-targeted radiopharmaceuticals such as technetium-labeled tilmanocept may facilitate the diagnostic evaluation of these patients, to help spare them possible serious morbidity from full regional lymph node dissections.”

“We are pleased that we could present results from this comparative meta-analysis with Lymphoseek to the nuclear medicine physicians and industry experts at SNMMI, as

thousands of patients with head and neck cancer stand to benefit from accurate diagnostic evaluation of their condition. The study uses top-line results from our interim analysis of Lymphoseek in the NEO3-06 Phase 3 clinical trial in head and neck cancer, and those developed in a widely regarded, independent, multi-center study," said Mark Pykett, VMD, PhD, CEO of Navidea. "Our NEO3-06 Phase 3 trial is an important clinical trial in highlighting our belief that Lymphoseek may provide advances that could benefit thousands of patients with head and neck cancer. Assessment of the full data-set from the NEO3-06 trial continues, and we are working with the FDA to evaluate the submission of a supplemental NDA that may potentially augment the Lymphoseek label."

About the Meta-analysis

The study used meta-analysis to examine two key parameters for assessing performance of radiotracing agents in lymphatic mapping and the evaluation of nodal metastasis in SCC: False Negative Rate (FNR), the percentage of patients in whom the sentinel lymph node failed to correctly stage the patient; and overall accuracy (AC), the degree of correctness. All patients in both studies received sentinel lymph node biopsy and complete, elective dissection of head and neck lymph nodes, and all nodes were evaluated for the presence of tumor. Results for Lymphoseek indicated a FNR of 0.0256 (95% CI=0.001, 0.138; n=39); $p<0.0006$ as compared to radiolabeled sulfur colloid; the FNR for radiolabeled sulfur colloid was 0.10 (95% CI=0.027, 0.231; n=41). Overall accuracy for Lymphoseek was 0.99 (n=82; $P<0.0161$ against radiolabeled sulfur colloid). The overall accuracy for radiolabeled sulfur colloid was 0.97 (n=140).

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 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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