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Navidea Biopharmaceuticals Provides Progress Updates on Lymphoseek® Programs

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today provided updates on several programs and events relating to Lymphoseek® (technetium Tc 99m tilmanocept) Injection, including a head-to-head clinical study underway at the University of California, San Diego (UCSD). The UCSD study is comparing the level of discomfort experienced by breast cancer patients after injection of Lymphoseek or radiolabeled sulfur colloid in lymphatic mapping procedures. Navidea also highlighted updates on the European filing for Lymphoseek with the Marketing Authorization Application (MAA) and multiple upcoming medical and scientific presentations. Lymphoseek is a novel, receptor-targeted, small-molecule radiopharmaceutical approved by the U.S. Food and Drug Administration for use in lymphatic mapping to assist in the localization of lymph nodes draining a primary tumor in patients with breast cancer or melanoma.

Head-to-Head Clinical Study Comparing Injection Pain Associated with Radiolabeled Sulfur Colloid vs. Lymphoseek

The investigator-initiated study underway at UCSD marks the first prospective, randomized, double-blinded controlled clinical study to address the issue of injection site pain between two radiopharmaceuticals that are commonly used in lymphatic mapping procedures. It is designed to determine if patients receiving Lymphoseek experience the same or less pain following injection compared to radiolabeled sulfur colloid, and to measure the amount of discomfort that patients report during and after injection. The study is also exploring comparative performance characteristics such as amount of time to sentinel lymph node visualization on lymphoscintigraphy imaging prior to surgery, sentinel lymph node localization success and the number of tumor draining lymph nodes removed.

“Surgeons who perform sentinel lymph node biopsy procedures in breast cancer and melanoma patients focus not only on clinical outcomes, but on optimizing the patient’s overall experience during a vulnerable time,” said Anne Wallace, M.D., Professor of Surgery, UC San Diego School of Medicine; Director of the Comprehensive Breast Health Center; UC San Diego Moores Cancer Center, and Principal Investigator on the study. “It is well accepted that sentinel node injection can be painful. We designed this study to try to understand if Lymphoseek injection is less painful and could improve the patient experience.”

Dr. Wallace continued, “This study is also exploring additional technical outcomes with these imaging agents that may result in better standardization of the lymphatic mapping technique for surgeons. For example, lymphoscintigraphy imaging is frequently performed prior to surgery to facilitate surgical planning, but visualization of tumor-draining lymph nodes using

conventional agents can vary, and is known to decrease with increasing patient age and weight. Further evaluation in this prospective study with controlled imaging time points can help us verify previously collected preliminary data, to enable more informed surgical protocols."

Lymphoseek Marketing Authorization Application (MAA) Update

Navidea has also made progress with the Lymphoseek Marketing Authorization Application (MAA) in Europe. Following Navidea's presentation of Oral Explanations to the European Medicines Agency's ("EMA") Committee for Medicinal Products for Human Use ("CHMP") on March 19, 2014, the Company anticipates that CHMP will convene the Scientific Advisory Group on Oncology (SAG-O) to discuss additional elements of the Lymphoseek clinical study in patients with head and neck cancer. The SAG-O meeting will provide an opportunity for Navidea and independent experts in head and neck cancer surgery to review clinical data in the MAA filing and discuss broad aspects of care for patients with head and neck cancer in Europe. During this process, the MAA remains active and the review clock will continue to be stopped while Navidea works with the CHMP to continue expanded discussions.

Scientific Advisory Groups (SAGs) are created by the CHMP to provide independent advice on scientific/technical matters relating to products under evaluation by the CHMP, or on any other scientific issue relevant to the work of the CHMP that relates to this area. The SAG, appointed by CHMP, will include clinicians and experts in the field of head and neck surgery and oncology. The CHMP, while taking into account the position expressed by the SAG, remains responsible for its final opinion.

Lymphoseek Presentations at Upcoming Scientific Conferences

Results from Lymphoseek studies will be presented at the following conferences in April and May.

6th European Congress on Head and Neck Oncology

April 24-26, 2014, Liverpool, UK

Oral Presentation: *Receptor-targeted ^{99m}Tc-tilmanocept For Sentinel Lymph Node Biopsy (SLNB) In HNSCC: Predictive Utility Vs. Elective Neck Dissection*

Author: Stephen Y. Lai, MD PhD, FACS, The University of Texas MD Anderson Cancer Center, Houston, TX

American Society of Breast Surgeons

April 30 – May 4, 2014, Las Vegas, Nevada

Poster Title: *Sensitivity and specificity of ^{99m}Tc-tilmanocept, a CD206-targeted molecular sentinel node mapping agent in breast cancer*

Author: Anne Wallace, MD, Professor of Surgery, UC San Diego School of Medicine; Director of the Comprehensive Breast Health Center; UC San Diego Moores Cancer Center

The Company further announced that 12 Lymphoseek and Manocept™ platform abstracts

from Navidea and collaborators will be presented at the 2014 Annual Meeting of the Society of Nuclear Medicine and Molecular Imaging (SNMMI) in June 2014. Additional information will follow in a subsequent release.

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 (FDA) 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 and is currently in review with the FDA.

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.

Navidea Biopharmaceuticals
Brent Larson, Executive VP & CFO, 614-822-2330
or
Sharon Correia, Associate Director, Corporate Communications, 978-655-2686

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