March 13, 2013

FDA Approves Navidea's Lymphoseek® (technetium Tc 99m tilmanocept) Injection for Use in Lymphatic Mapping

The first receptor-targeted radiopharmaceutical approved for lymphatic mapping in breast cancer and melanoma patients

Company to Host Conference Call at 4:00 p.m., March 13, 2013

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced U.S. Food and Drug Administration (FDA) approval of Lymphoseek® (technetium Tc 99m tilmanocept) Injection, a novel product indicated for use in lymphatic mapping procedures to assist in the localization of lymph nodes draining a primary tumor in patients with breast cancer or melanoma. Lymphoseek is a receptor targeted radiopharmaceutical designed to identify these lymph nodes which have the highest probability of harboring cancer and thereby assist physicians in the staging of such patients.

Lymphatic mapping is a procedure in which lymph nodes that may contain tumor metastases are identified and biopsied to determine if cancer has spread beyond the primary tumor. Accurate staging of lymph nodes 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 and 77,000 new cases of melanoma are expected to be diagnosed in the United States in 2013.[1]

"We recommend lymphatic node mapping and sentinel node biopsy for patients with early stage breast cancer and in select cases of ductal carcinoma in situ," said Anne Wallace, M.D., Professor of Surgery, UC San Diego School of Medicine; Director of the Breast Care Unit; UC San Diego Moores Cancer Center; and Principal Investigator for breast cancer in the Lymphoseek Phase 3 clinical trials. "The ability to reliably identify multi-node pathology-positive patients is important to optimize their post-surgery management and to spare certain patients from unnecessary surgery and potentially debilitating side effects. Products specifically designed to address reliable lymph node uptake and retention can provide significant clinical utility and help standardize the process of lymph node mapping."

"Both the incidence rate and the death rate for melanoma continue to increase, in the United States and in many other parts of the world," said Vernon K. Sondak, M.D., Chair, Department of Cutaneous Oncology, Moffitt Cancer Center, Tampa Fla., and Principal Investigator for melanoma in the Lymphoseek Phase 3 clinical trials. "Most patients present with clinically localized disease, but microscopic metastases to the regional lymph nodes are common and are the major prognostic factor for these patients. Over the past 20 years, surgical staging of the regional nodes with intraoperative lymphatic mapping and sentinel

node biopsy has emerged as the worldwide standard of care for patients with clinically node-negative intermediate and thick melanomas, and for selected patients with higher-risk thin primaries as well. New technologies offer the promise of improving intraoperative lymphatic mapping, allowing procedures to be done more quickly and potentially lessening the risk of misclassifying patients as node-negative when in fact their tumor has already spread to the regional nodes."

The approval of Lymphoseek is based on data from more than 540 subjects receiving Lymphoseek. In pivotal Phase 3 studies that were conducted in 332 patients with either breast cancer or melanoma, Lymphoseek, on average, was present in 97% (range 94-100%) of resected, histology-confirmed lymph nodes. To date, no clinically significant drug-related adverse reactions have been reported. Lymphoseek has no contraindications and the most common adverse reactions were injection site irritation and/or pain (<1%).

"We believe today's approval of Lymphoseek validates our ability to advance the field of precision diagnostics," said Mark J. Pykett, V.M.D., Ph.D., President and CEO of Navidea. "Our vision is to improve diagnostic accuracy, clinical decision-making and patient care. We are gratified that our scientific achievements may benefit thousands of patients diagnosed with breast cancer and melanoma each year. We look forward to continuing the development of Lymphoseek into additional indications and to progressing our oncology and neurology pipeline."

Lymphoseek will be sold and distributed in the U.S. on an exclusive basis by Cardinal Health, Inc. As part of the distribution agreement, Cardinal Health's Nuclear Pharmacy Services business will be responsible for commercializing and dispensing Lymphoseek to health care professionals who are involved in lymphatic mapping. Navidea is also working to identify and partner with distributors in other markets outside of the U.S. Navidea will play an ongoing role in commercial activities through focused deployment of medical science liaison and medical education activities. This is consistent with Navidea's overall strategy to remain involved in market-based activities with its products while leveraging the extensive capabilities and infrastructure of partners around the world.

Conference Call for Investors

Navidea Biopharmaceuticals will host a conference call for investors, today at 4:00 p.m. EDT to discuss FDA's approval of Lymphoseek. Conference call dial-in details will be announced this afternoon.

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 stage 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, in patients with breast cancer or melanoma.

Lymphatic mapping is a procedure in which lymph nodes that may contain tumor metastases are identified and biopsied to determine if cancer has spread beyond the primary tumor. Accurate staging of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. Lymphoseek was approved for use by the FDA on March

13, 2013. According to the American Cancer Society, approximately 232,000 new cases of breast cancer and 77,000 new cases of melanoma are expected to be diagnosed in the United States in 2013.

About Lymphatic Mapping

Lymphatic mapping is a procedure designed to guide lymph node dissection and biopsy procedures. It consists of Intraoperative Lymphatic Mapping (ILM) often accompanied by lymphoscintigraphy. Lymphoscintigraphy is an imaging procedure routinely performed pre-operatively to provide guidance on the location of lymph nodes to be biopsied. ILM is a surgical procedure in which lymph nodes draining the area around a tumor are identified and biopsied to determine if cancer has spread to the lymph nodes. These nodes, commonly referred to as “Sentinel Lymph Nodes,” are removed and analyzed for the presence of malignant cells. Lymphatic Mapping provides an accurate staging procedure that can help ensure optimal surgical and therapeutic choices, including the avoidance of the morbidity of a complete lymph node dissection for patients in whom the Sentinel Lymph Nodes were found to be free of cancer.

Indication and Important Safety Information About Lymphoseek

Indication

Lymphoseek (technetium Tc 99m tilmanocept) Injection is indicated for lymphatic mapping 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.

[1] ACS Cancer Facts & Figures, 2013

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