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Lymphoseek® Data Presented in European Medical Conference Reinforces Clinical Value in Head & Neck Cancer of the Oral Cavity

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) today reported that a Lymphoseek® (technetium Tc 99m tilmanocept) injection presentation at the International Conference on Innovative Approaches in Head and Neck Oncology contributes to a growing body of data reinforcing the clinical value of Lymphoseek, specifically for guiding sentinel lymph node biopsy in head and neck cancer patients with squamous cell carcinoma of the oral cavity. The data, presented by Remco de Bree, M.D., Ph.D. head and neck surgeon from the VU University Medical Center, The Netherlands, included the following:

- Lymphoseek is uniquely suited to identify the sentinel lymph node where the injection site is in very close proximity
- Previously reported clinical trial data, which were used to obtain European approval in 2014 and which demonstrated a 2.56% false negative rate for sentinel lymph node detection compared to the gold standard of post-operative histopathology
- There was no observable difference in Lymphoseek performance when used either the day prior to or the day of surgery
- Lymphoseek displayed a favorable safety profile and delivered rapid and consistent injection site clearance and localization to sentinel nodes.

“Not only was the detection rate of sentinel nodes by Lymphoseek high, but it has other advantages,” said Professor de Bree. “Where other tracers have problems in identifying and harvesting of sentinel nodes when there is a close spatial relation between injection site and sentinel node, which is pronounced in floor of mouth tumors, tilmanocept facilitated accurate prediction of the spread of the cancer in all oral cavity sites. With the recent approval of Lymphoseek, surgeons are no longer limited to en-bloc surgery of all the soft tissue in a lymph node region.”

“These data provide further support to the clinical value of Lymphoseek to the surgical oncologist, reinforcing the rationale to incorporate Lymphoseek in sentinel lymph node biopsy procedures,” said Michael Tomblyn, M.D., Executive Medical Director for Navidea. “The product offers surgeons in both the U.S. and Europe an alternative that can reduce surgical requirements and may reduce patient morbidity, in particular where the injection site is close to the at-risk sentinel node, as is the case with cancers of the oral cavity as well as breast cancer and malignant melanoma.”

About Lymphoseek

Lymphoseek® (technetium Tc 99m tilmanocept) injection is the first and only FDA-approved receptor-targeted lymphatic mapping agent. It is a novel, receptor-targeted, small-molecule radiopharmaceutical used in the evaluation of lymphatic basins that may have cancer involvement in patients. Lymphoseek is designed for the precise identification of lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. Lymphoseek is approved by the U.S. Food and Drug Administration (FDA) for use in solid tumor cancers where lymphatic mapping is a component of surgical management and for guiding sentinel lymph node biopsy in patients with clinically node negative breast cancer, melanoma or squamous cell carcinoma of the oral cavity. Lymphoseek has also received European approval in imaging and intraoperative detection of sentinel lymph nodes in patients with melanoma, breast cancer or localized squamous cell carcinoma of the oral cavity.

Accurate diagnostic evaluation of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. Overall in the U.S., solid tumor cancers may represent up to 1.2 million cases per year. The sentinel node label in the U.S. and Europe may address approximately 235,000 new cases of breast cancer, 76,000 new cases of melanoma and 45,000 new cases of head and neck/oral cancer in the U.S., and approximately 367,000 new cases of breast cancer, 83,000 new cases of melanoma and 55,000 new cases of head and neck/oral cancer diagnosed in Europe annually.

EU Lymphoseek® Indication and Important Safety Information

Radiolabelled Lymphoseek is indicated for imaging and intraoperative detection of sentinel lymph nodes draining a primary tumour in adult patients with breast cancer, melanoma, or localised squamous cell carcinoma of the oral cavity.

External imaging and intraoperative evaluation may be performed using a gamma detection device.

Important Safety Information about Lymphoseek for EU & U.S. patients

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.

Any radiation-emitting product may increase the risk for cancer. Adhere to dose recommendations and ensure safe handling to minimize the risk for excessive radiation exposure to patients or health care workers. In clinical trials, no patients experienced serious adverse reactions and the most common adverse reactions were injection site irritation and/or pain (<1%).

Prescribing information and more information about Lymphoseek for EU patients will be

available at: http://ec.europa.eu/health/documents/community-register/index_en.htm.

For full prescribing information and more information about Lymphoseek for U.S. patients, please visit: 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, therapeutics and radiopharmaceutical agents. Navidea is developing multiple precision-targeted products and platforms including Manocept™, NAV4694, and NAV5001, to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making, targeted treatment and, ultimately, patient care. Lymphoseek®(technetium Tc 99m tilmanocept) injection, Navidea's first commercial product from the Manocept platform, was approved by the FDA in March 2013 and by the EMA in November 2014. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel radiopharmaceutical agents and therapeutics, 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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