September 18, 2014

Navidea Receives Orphan Drug Designation from FDA for Use of Lymphoseek® in Head and Neck Cancers

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) today announced that Lymphoseek® (technetium Tc 99m tilmanocept) Injection has been granted Orphan Drug Designation by the U.S. Food & Drug Administration (FDA) for use in sentinel lymph node detection in patients with cancer of the head and neck. The designation is based upon an estimated 40,000 procedures being performed in this patient population. The FDA Office of Orphan Products Development (OOPD) mission is to advance the evaluation and development of products (drugs, biologics, devices, or medical foods) that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions.

“This Orphan Drug designation provides further validation of Lymphoseek for sentinel lymph node detection, underscores the need for new innovations in the treatment of patients with head and neck cancer, and, importantly strengthens Navidea’s competitive position by providing seven years of market exclusivity in this indication," said Michael Goldberg M.D., Navidea Interim CEO. "This decision follows the FDA Fast Track designation, Priority Review and subsequent sNDA approval of Lymphoseek for guiding sentinel lymph node biopsy in head and neck cancer patients with squamous cell carcinoma of the oral cavity.”

The FDA Orphan Drug Designation program provides a special status to drugs and biologics intended to treat, diagnose or prevent rare, or ‘orphan’, diseases and disorders, defined as affecting fewer than 200,000 people in the U.S. This designation provides for a seven-year marketing exclusivity period against competition in head and neck cancers as well as certain incentives, including federal grants, tax credits and a waiver of PDUFA filing fees, which qualifies the Company to request a refund of previously paid filing fees of up to $1.1 million.

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 with breast cancer, melanoma and head and neck cancer patients with oral cavity carcinoma. 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 lymphatic mapping to assist in the localization of lymph nodes draining a primary tumor in patients with breast cancer or melanoma and for use in guiding sentinel lymph node biopsy in head and neck cancer patients with squamous cell carcinoma of the oral cavity. The Company anticipates continuing development of Lymphoseek into other solid tumor areas.

Lymphoseek Indication and Important Safety Information

Lymphoseek (technetium Tc 99m tilmanocept) Injection is indicated, using a hand-held gamma counter, for:

- Lymphatic mapping to assist in the localization of lymph nodes draining a primary tumor site in patients with breast cancer or melanoma;
- Guiding sentinel lymph node biopsy, in patients with clinically node negative squamous cell carcinoma (SCC) of the oral cavity.

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.

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%).

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 Manocept™, NAV4694, NAV5001, 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 Tc 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

Source: Navidea Biopharmaceuticals, Inc.