April 4, 2016

Navidea Updates Clinical Development Plan for Diagnostic Use of Lymphoseek® IV in Rheumatoid Arthritis

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAVB) announced today that based on its very recent meeting with the U.S. Food and Drug Administration (FDA), the Company will begin the clinical trial development process for its intravenous (IV) injection protocols for use of Lymphoseek® (technetium Tc 99m tilmanocept) injection in rheumatoid arthritis (RA) and other disease states. Lymphoseek is Navidea's first commercial product from its Manocept™ platform.

"Our efforts to continue to unlock the significant value of the Manocept platform are well underway as we seek to expand Lymphoseek's label so it can be used as an immunodiagnostic for additional diseases," said Rick Gonzalez, President and CEO of Navidea. "This collaborative meeting with FDA has enabled us to continue to advance the regulatory process and begin to implement our clinical program in rheumatoid arthritis, an indication that has an addressable market that is substantially larger than the current Lymphoseek indications. We look forward to reporting our progress throughout the year."

Over the past year Navidea conducted a series of meetings and communications with the FDA to gain clarity on a path to extend the current Lymphoseek IND to support IV administration of Lymphoseek. In parallel the Company initiated its clinical development efforts and has already completed six required non-clinical animal studies for this new route of administration, submitted the summary results in a briefing package to the FDA, and secured NIH grants in RA and Kaposi's Sarcoma, worth up to $3.8 million to support further development through Phase 2 studies.

Based upon the feedback from the latest meeting, Navidea expects to submit an IND amendment to the FDA that will allow initiation of Phase 1/2 IV studies of Lymphoseek. The addition of this new route of administration would enable further development of Lymphoseek in broader immunodiagnostic disease applications including rheumatoid arthritis. The timing is expected to be consistent with Navidea's previously disclosed development plans to initiate a multi-center Phase 1/2 registrational trial employing IV-administration to evaluate Lymphoseek for the primary diagnosis of rheumatoid arthritis and to aid in the differential diagnosis of rheumatoid arthritis from other types of inflammatory arthritis during the second half of 2016. In addition, we expect to begin the Phase 1 pilot trial evaluating subcutaneous injection of Lymphoseek in active RA subjects in the second quarter of 2016.

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 results guide therapy decisions and determine 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 600,000 new cases of breast cancer, 160,000 new cases of melanoma and 100,000 new cases of head and neck/oral cancer diagnosed annually.

Lymphoseek Indication and Important Safety Information

Lymphoseek is a radioactive diagnostic agent indicated with or without scintigraphic imaging for:

• Lymphatic mapping using a handheld gamma counter to locate lymph nodes draining a primary tumor site in patients with solid tumors for which this procedure is a component of intraoperative management.

• Guiding sentinel lymph node biopsy using a handheld gamma counter in patients with clinically node negative squamous cell carcinoma of the oral cavity, 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.

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

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. Navidea is developing multiple precision-targeted products and platforms including Manocept™ and NAV4694 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 in Europe in November 2014. The development activities of the Manocept immunotherapeutic platform will be conducted by Navidea in conjunction with its subsidiary, Macrophage Therapeutics. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel products and advancing the Company's pipeline through 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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