January 6, 2016

Navidea Biopharmaceuticals Enrolls First Patient in Pediatric Trial of Lymphoseek®

- *Study to Evaluate Lymphoseek in a Pediatric Population in Melanoma, Rhabdomyosarcoma, or Other Solid Tumors* ***-***

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), today announced that the first pediatric patient was enrolled in a clinical study comparing Lymphoseek® (technetium Tc 99m tilmanocept) injection and vital blue dye (VBD) in a pediatric population of patients with melanoma, rhabdomyosarcoma, or other solid tumors. The study is designed to investigate how Lymphoseek compares with VBD in identifying lymph nodes as well as evaluate safety and tolerability in the pediatric population. Lymphoseek is designed for the precise identification of lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer and is approved for adult use only. Enrollment is currently planned at approximately six sites throughout the U.S. The first patient has been enrolled by the Nationwide Children's Hospital in Columbus, OH.

“We are pleased to participate in this important clinical study of Lymphoseek in the pediatric patient population where no lymph node mapping agents have yet been approved,” said Jennifer Aldrink, M.D., Assistant Professor of Clinical Surgery, The Ohio State University College of Medicine and Director of Surgical Oncology, Division of Pediatric Surgery at Nationwide Children's Hospital in Columbus, OH. “Intraoperative Lymphatic Mapping (ILM) and Sentinel Lymph Node Biopsy (SLNB) are standards of care in adult and pediatric patients in several forms of cancer, and Lymphoseek is a new agent being used in many adult centers as an alternative to sulfur colloid formulation. Lymphoseek may have the potential to aid physicians in evaluating lymph nodes in children that are necessary for accurate disease staging and optimal post-surgical treatment.”

“This study will provide further data on the overall clinical value of Lymphoseek, which has already shown to be a highly effective immunodiagnostic tool in adult patients. Medical literature supports the importance of lymph node evaluations in pediatric patients with rhabdomyosarcoma and melanomas noting that lymph node metastases are highly associated with poorer survival,” said Michael Tomblyn, M.D., Chief Medical Officer of Navidea. “Until now, there have been few studies of ILM and SLNB in children. We look forward to the opportunity to evaluate Lymphoseek’s use in pediatric populations.”

This study (NAV3-18) is a prospective, open-label, multicenter study comparing Lymphoseek® and VBD as lymphoid tissue targeting agents in pediatric patients with melanoma, rhabdomyosarcoma, or other solid tumors who are undergoing lymph node mapping. Primary goals of this study are to evaluate safety and tolerability of Lymphoseek in this subject population and determine the concordance of in vivo detection rates of Lymphoseek and of VBD in tissue excised and histologically confirmed as lymph nodes. In addition, the study will measure other efficacy signals including assessment of the identified

lymph node(s) to confirm: the presence/absence of tumor metastases; agent localization per tumor type; degree of localization (nodes per subject both intraoperatively and with preoperative SPECT/CT); reverse concordance parameters; change of subject stage based on histopathology and descriptive assessment on change in treatment plan; number of lymph nodes detected with Lymphoseek intraoperatively compared with preoperative SPECT/CT imaging.

Information on the protocol and enrolling sites for this study (NAV3-18) can be found at: https://www.clinicaltrials.gov/ct2/show/NCT02509598?term=lymphoseek&rank=7

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), with or without scintigraphic imaging, 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.

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. 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.

View source version on businesswire.com:
http://www.businesswire.com/news/home/20160106005427/en/

Navidea Biopharmaceuticals
Investors
Tom Baker, 617-532-0624
tbaker@navidea.com
or
Media
Sharon Correia, 978-655-2686
Associate Director, Corporate Communications
or
David Shull or Chris Hippolyte, 858-717-2310
david.schull@russopartnersllc.com
Chris.hippolyte@russopartnersllc.com

Source: Navidea Biopharmaceuticals, Inc.