February 2, 2016

Navidea Provides Update on Lymphoseek® and Immunodiagnostics Development Pipeline

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAVB), today provides an update on its commercial and clinical development efforts with respect to its Lymphoseek® (technetium Tc 99m tilmanocept) injection, the first and only FDA-approved receptor-targeted lymphatic mapping agent, and the Manocept™ immunodiagnostic development pipeline.

2015 Commercial Highlights

In 2015, the Company created and executed a new commercialization strategy for Lymphoseek to better leverage the label expansion approved by the FDA in October 2014 and, over time, accelerate its market penetration. This included a complete refresh of the brand, moving away from a feature-based selling approach to a customer-centric one focused on the benefits to the surgeon and patient.

In concert with the rebranding efforts, the Company also recruited, hired and trained a new salesforce in the latter part of the second quarter of 2015. The new direct sales team focused on targeting the highest priority territories. The Company anticipated the sales team's contributions would be most significant starting the fourth quarter of 2015 and onward based on the four- to six-month sales cycle of Lymphoseek.

The initial launch of the new commercialization strategy resulted in the following during 2015:

- Grew sales by 141% year over year, based on preliminary unaudited Lymphoseek sales to Navidea of $10.2 million for 2015 representing total brand revenue of approximately $20 million;
- Ended the year at an annualized sales run rate for Lymphoseek of over $15 million in revenue to Navidea, which does not reflect the opportunity for additional growth in existing and expansion sales territories throughout 2016;
- Achieved an increase of 55% in "average daily doses sold" from the end of 2014 through the end of 2015;
- Increased penetration into large accounts - nearly tripling the number of accounts that averaged more than 20 doses per month in 2015 versus 2014; and,
- Expanded the network of cancer centers and hospitals that use or plan to use Lymphoseek which now includes 17 of the top 20 US Best Hospitals for Adult Cancer as reported by the most recent U.S. News and World Report.

Rick Gonzalez, President and Chief Executive Officer, said, "We enter 2016 with positive

momentum behind our new commercialization strategy. We expect our sales team's strong contributions to continue to accelerate product revenues throughout the year. In addition, European sales revenues are expected to be generated from commercialization efforts to begin in the fourth quarter. In parallel, our R&D team is aggressively advancing our immunodiagnostics pipeline focused on significantly larger market opportunities including Rheumatoid Arthritis (RA), which has a prevalence of approximately 3.8 million patients in the U.S. and Europe. We will share additional details on our plans for 2016, including an update on Macrophage Therapeutics and the sale of NAV4694, during our upcoming year-end earnings conference call."

Clinical Development Update

The Company continues to work toward a more focused development program using its Manocept platform in immunodiagnostics, including the FDA label expansion for Lymphoseek (*Tc99m tilmanocept)* into RA and Kaposi's sarcoma (KS). Importantly, the costs of these development programs will be defrayed by NIH grants awarded to the Company in 2015 totaling over $3.8 million.

In the next 90 days, the Company intends to:

- Advance Lymphoseek Label Expansion into RA:
    - Meet with the FDA before the end of March 2016 to share preclinical results on the intravenous route of administration (IVROA) and discuss and agree on the Phase 1 and 2 clinical plan for our Rheumatoid Arthritis (RA) immunodiagnostic program. This is a follow-up meeting to the one that took place in May 2015, where the Company and the FDA confirmed requirements for a preclinical submission package for the use of Lymphoseek in IVROA; and,
    - Finalize preparations to initiate a Phase 1 pilot trial evaluating subcutaneous injection of *Tc99m tilmanocept* in active RA subjects in the first half of 2016. During the second half of 2016, the Company intends on initiating a subsequent Phase 1/2 registrational trial of IV-administered *Tc99m tilmanocept* for the RA immunodiagnostic application.
- Support the existing Lymphoseek label in Lymphatic Mapping:
    - Expand patient enrollment in the FDA/EMA mandated pediatric trial for children with melanoma, rhabdomyosarcoma, or other solid tumors who are undergoing lymph node mapping and who meet special criteria for pediatric sentinel node biopsy. Since the first patient was dosed in December 2015, two new sites have been added including Cincinnati Children's Hospital Medical Center;
    - Enroll first patient at the MD Anderson Cancer Center in the Company's multi–center cervical cancer study;
    - Initiate patient enrollment in the Investigator Initiated Study (IIS) endometrial cancer study directed by Dr. Michael McHale at UC San Diego Health System; and,
    - Expand patient enrollment in the cardiovascular immunodiagnostic study, an IIS study in collaboration with Massachusetts General Hospital. Based on encouraging findings in the first patients dosed, we are very excited by the potential and are seeking to accelerate and expand this funded program using a protocol for IVROA.

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. 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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