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Navidea Receives $1.1Million PDUFA Filing Fee Refund for Award of Orphan Drug Status; Platinum Partners Reaffirms Commitment to Line of Credit

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAVB) today announced it has received a $1.1 million refund of the previously paid Prescription Drug User Fee Act (PDUFA) filing fee related to the granting of orphan drug status of Lymphoseek® (technetium Tc 99m tilmanocept) injection in head and neck cancers. Lymphoseek was granted Orphan Drug Designation by the FDA in September 2014 for use in sentinel lymph node detection in patients with cancer of the head and neck. Additionally, Platinum Partners, Navidea's major investor, reaffirmed its support of the Company through the remaining $31.8 million available under the previously announced line of credit.

"We share Navidea's belief in Lymphoseek's commercial potential and the diagnostic and therapeutic promise of the Manocept™ platform," said Mark Nordlicht, Chief Investment Officer, Platinum Partners. "Following recent regulatory approvals and the hiring of Rick Gonzalez as CEO, we are fully committed to providing the organization with access to the outstanding line of credit. While Platinum believes the Company's financial strength will improve with each day's sales under the new broader label, we are confident this funding vehicle is in the best interest of shareholders and access to it, to the extent that it becomes necessary, can minimize Navidea's cost of capital."

"We believe we have sufficient capital resources to attain our immediate goals and realize the full commercial potential for Lymphoseek," said Rick Gonzalez, Navidea Chief Executive Officer. "We are in a position to manage our available cash with our expected growth in revenue and gross profit, our ability to further reduce our operating costs and, if needed, our access to capital under the line of credit from Platinum Partners."

The original line of credit was executed on July 26, 2012 with Platinum Partners, (formerly Platinum-Montaur Life Sciences, LLC). Under the terms of the transaction, Platinum Partners originally committed to extend up to $15 million in debt immediately to the Company, with an additional $20 million which became committed upon approval of Lymphoseek, and yet an additional $15 million potentially available on terms to be negotiated. To date, the Company has drawn $3.2 million under the credit facility. No conversion features or warrants are associated with the facility.

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 been recommended by CHMP for European approval in sentinel lymph node detection for melanoma, breast cancer or 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 U.S. 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 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, 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.

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