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Navidea Biopharmaceuticals Announces Presentation of Lymphoseek® Three-Year Recurrence and Survival Outcomes after Sentinel Lymph Node Biopsy in Patients with Breast Cancer and Melanoma

- Results Presented at Society of Surgical Oncology Cancer Symposium Indicate Low Regional Recurrence and High Disease-Specific Survival Rates -

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced results of a three-year, voluntary follow-up study of Lymphoseek® (technetium Tc 99m tilmanocept) Injection conducted in patients who participated in a Phase 3 clinical trial (NEO3-05) of the product. The primary objective of the follow-up study was to determine the regional (i.e., draining lymph node basin) recurrence-free rate (RRFR) after sentinel lymph node biopsy with Lymphoseek. Results of the follow-up study indicated that in patients who were confirmed to be node-negative (N0) after sentinel lymph node biopsy (n=88; 49 breast cancer, 39 melanoma) the RRFR was 98.8% (100% in breast cancer; 97.4% in melanoma) and the disease-specific survival rate (DSSR) was 98.6% (97.8% in breast cancer; 100% in melanoma) at three years. The results, presented by Stephen P. Povoski, MD, of The Ohio State University Wexner Medical Center, will also be highlighted in a Grand Rounds presentation as one of several Lymphoseek presentations at SSO 2014, the 67th Society of Surgical Oncology Annual Cancer Symposium, in Phoenix, Arizona. Lymphoseek is a novel, receptor-targeted, small-molecule radiopharmaceutical approved by the U.S. Food and Drug Administration for use in lymphatic mapping to assist in the localization of lymph nodes draining primary tumor in patients with breast cancer or melanoma

Findings from the Lymphoseek follow-up study compare favorably with outcomes from previously reported data from other studies. A study reported in the *New England Journal of Medicine* which evaluated the use of sentinel node biopsy or nodal observation node-negative (N0) melanoma patients[1] showed a DSSR at three years of 90.1%. In another study published in *Lancet Oncology*[2], node-negative (N0) breast cancer patients had an estimated disease-free survival rate at five years of 88.6%.

“Sentinel lymph node biopsy is well-established as an appropriate alternative to full lymph node dissection in node-negative, early-stage breast cancer and melanoma patients, and it can spare patients of the resultant morbidities associated with full lymph node dissection,” said Dr. Povoski. ”This three-year follow-up analysis was performed to assess outcomes associated with Lymphoseek-guided sentinel lymph node removal. Our findings support the

contention that Lymphoseek, which has previously been shown to accurately identify tumor-draining sentinel lymph nodes in both early-stage breast cancer and melanoma patients, results in a very high detection rate, with patient outcome at three years of follow up demonstrating a very low recurrence rate and a high survival rate."

"Surgeons are acutely aware of the importance of accurate diagnostic evaluation in assessing their patients' conditions, and we are pleased that these results from the Lymphoseek NEO3-05 follow-up study are being made available to surgeons attending the prestigious Society of Surgical Oncology Cancer Symposium," said Cornelia Reininger, MD, PhD, Senior Vice President and Chief Medical Officer of Navidea. "We believe these results underscore the important role of Lymphoseek in providing physicians with critical information, since for those breast cancer and melanoma patients overall whose nodes were determined to be free of cancer at the beginning of the study, 98.8% did not have any cancer in their lymph nodes after three years."

In a second presentation at the meeting, Dr. Jennifer Baker of the University of California, San Diego presented results from combined efficacy analyses of three Phase 3 Lymphoseek clinical trials in breast cancer, melanoma and head and neck cancer patients. The data showed that Lymphoseek demonstrated high sensitivity, as well as high negative predictive value and accuracy in identifying tumor-draining lymph nodes, and that it is likely to be predictive of pathological staging.

Both poster presentations can be viewed in the Publications section of Navidea website located at:
http://www.navidea.com/development-programs/publications/bibliography.html

About Lymphoseek®

Lymphoseek® (technetium Tc 99m tilmanocept) Injection is a novel, receptor-targeted, small-molecule radiopharmaceutical used in lymphatic mapping procedures that are performed to help in the diagnostic evaluation of potential cancer spread for patients with breast cancer and melanoma. Lymphoseek is designed to identify the lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. Lymphoseek was approved by the U.S. Food and Drug Administration (FDA) in March, 2013 for use in lymphatic mapping to assist in the localization of lymph nodes draining a primary tumor in patients with breast cancer or melanoma. The Company anticipates continuing development of Lymphoseek into other solid tumor areas that may include head and neck cancers, prostate cancer, thyroid cancer, lung/bronchus cancers, colorectal cancer and others. Lymphoseek was granted Fast Track and Priority Review designation for its sNDA for sentinel lymph node detection in patients with head and neck cancer and is currently in review with the FDA.

Accurate diagnostic evaluation of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. According to publicly available information, approximately 235,000 new cases of breast cancer, 76,000 new cases of melanoma and 69,500 new cases of head and neck/oral cancer are expected to be diagnosed in the United States in 2014, and approximately 367,000 new cases of breast cancer, 83,000 new cases of melanoma and 137,000 new cases of head and neck/oral cancer diagnosed in Europe annually.

U.S. Indication and Important Safety Information About Lymphoseek

Indication

Lymphoseek (technetium Tc 99m tilmanocept) Injection is a lymphatic mapping agent indicated for use with a hand-held gamma counter to assist in the localization of lymph nodes draining a primary tumor site in patients with 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.

The most common adverse reactions are injection site irritation and/or pain (<1%).

FULL LYMPHOSEEK PRESCRIBING INFORMATION CAN BE FOUND AT: WWW.LYMPHOSEEK.COM

[1]Morton, DL, Thompson JF, Cochran AJ, et al. Sentinel-Node Biopsy or Nodal Observation in Melanoma. *N Engl J Med* 2006;355:1307-1317.

[2]Krag DN, Anderson SJ, Julian TB, et al. Sentinel-lymph-node resection compared with conventional axillary-lymph-node dissection in clinical node-negative patients with breast cancer: overall survival findings from the NSABP B-32 randomised phase 3 trial. *Lancet Oncol* 2010;11(10):927-933.

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 NAV4694, NAV5001, Manocept™ 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 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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