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Navidea Biopharmaceuticals Presents New Data on Precision Diagnostic Platform at Harvard Conference

- Proof-of-principle data marks expansion of the Navidea Manocept™ platform -

- Company executives discuss precision diagnostics in panel sessions -

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAV), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, presented collaborative data at the Cancer Advance Conference at Harvard Medical School from proof-of-principle imaging studies using tilmanocept-Cy3, a fluorescent-labeled agent from the Company's Manocept™ platform, utilizing technical principle underlying Navidea's FDA-approved lymphatic mapping product, Lymphoseek® (technetium 99m tilmanocept) Injection. Data presented at the conference establish the feasibility of using Manocept compounds to bind to the CD206 mannose receptor and target macrophage inflammatory cells, an approach that may enable the design of novel immune cell-targeted agents for diagnosis and disease staging.

These studies using human tissue, animal model and in vitro analyses focused on establishing the ability of fluorescent tilmanocept-Cy3 to target macrophages in two disease states which are representative of broader macrophage-associated disorders: Kaposi's Sarcoma (KS) and Tuberculosis (TB), both outside the current lymphatic mapping application. These data support the expansion of the Manocept platform into potential new indications in macrophage-mediated disorders, utilizing immune-cell targeting to address unmet diagnostic needs in this emerging area. Other recognized macrophage-mediated disorders include not only KS and TB, but rheumatoid arthritis, Systemic Lupus Erythematosus, atherosclerosis/vulnerable plaque, Crohn's disease and others that span clinical areas in oncology, autoimmunity, infectious diseases, cardiology, and inflammation.

"Today's conference emphasized the medical need for innovative precision diagnostics in the pursuit of better patient outcomes in a range of diseases," commented Dr. Mark Pykett, Navidea CEO. "With the US approval and commercialization of our Lymphoseek product using CD206-targeting technology, we believe now is an opportune time to unveil the extension of our platform to promising new areas. These newly developed data suggest that our Manocept platform represents an opportunity to exploit the CD206-targeting mechanism underlying Lymphoseek and focus on new areas of diagnostic need beyond lymphatic mapping. We are encouraged by these data, provided by key experts in the field, supporting this principle. We intend to continue to evaluate emerging data in other disease states to define areas of focus, development pathways and partnering options to capitalize on this innovative platform," added Dr. Pykett.

The Manocept Platform

Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on macrophages. Macrophages play important roles in many disease states and are an emerging target in many diseases where diagnostic uncertainty exists. This flexible and versatile platform acts as an engine for purpose-built molecules that may enhance diagnostic accuracy, clinical decision-making and ultimately patient care, while offering the potential to utilize a breadth of diagnostic modalities, including SPECT, PET, intra-operative and/or optical-fluorescence detection. The Company's FDA-approved precision diagnostic lymphatic mapping agent, Lymphoseek (technetium 99m tilmanocept) Injection, is representative of the ability to successfully exploit this mechanism to develop powerful, new diagnostic agents.

Data presented at the Harvard Conference focused on proof-of-principle studies in KS and TB. "With increased retroviral treatment resistance, the incidence of Kaposi Sarcoma appears to be growing, with the disease extending to other organs and tissues beyond skin. Unfortunately, there are few, if any, tumor-specific diagnostic options to determine if and where the tumor has spread from the skin, so patient staging and treatment regimens may not be optimally managed," commented Michael S. McGrath, MD, PhD, **Professor, Departments of Laboratory Medicine, Pathology, and Medicine, University of California, San Francisco**. "Having conducted research in macrophage-mediated disease pathogenesis for decades, I believe that CD206 targeting in general, and Manocept-derived molecules in particular, are potentially potent tools for addressing unmet needs in this area such as identifying, staging and assessing disease activity, and represents a platform that may be able to address broader disease states where macrophages are known to play a role."

The poster presentation entitled "*Targeting the Human Mannose Receptor (CD206) for Lesion Localization and Imaging in Kaposi's Sarcoma and Other Disorders*" highlights research from the labs of Navidea collaborators Dr. Michael McGrath of **UCSF and Drs. Larry Schlesinger and Wael Jarjour of The Ohio State University**. The studies evaluated the ability of tilmanocept-Cy3, a CD206-targeted imaging agent, to identify and localize specifically to macrophage CD206. Data presented included findings in KS studies that tilmanocept-Cy3 binds specifically to and localizes macrophage CD206 in KS lesions. In tumor tissue from over 60 KS patients, greater than 96% of KS tumor cells and tumor-associated macrophages expressed CD206 and bound and internalized tilmanocept-Cy3, affording a precise means of identifying these cells in KS lesions.

Data from an additional study in TB demonstrated similar binding and internalization in macrophages infected with *M. tuberculosis*, the causative mycobacterium in tuberculosis. These data suggest that the ability to target CD206 and identify disease-associated macrophages may potentially be broadly applicable in the development of new diagnostics. Additional data are currently being developed in rheumatoid arthritis. The Company anticipates publication of Manocept data in the coming weeks.

About Navidea Biopharmaceuticals Inc.

Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAV) is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. Navidea is actively developing four radiopharmaceutical agent

platforms – Lymphoseek[®] (technetium 99m tilmanocept) Injection, NAV4694, NAV5001 and RIGScan[™] – to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and, ultimately, patient care. Navidea's first commercial agent, Lymphoseek, 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.

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 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.

Accurate diagnostic evaluation of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. According to the American Cancer Society, approximately 232,000 new cases of breast cancer, 77,000 new cases of melanoma and 67,000 new cases of head and neck/oral cancer are expected to be diagnosed in the United States in 2013.

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%).

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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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