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Navidea to Collaborate with Maimonides Medical Center on Clinical Trial Utilizing Lymphoseek® for Lymphatic Mapping in Colorectal Cancer

– Study will evaluate use of Lymphoseek to pinpoint lymph nodes most likely to contain cancer –

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced it has entered into an agreement to collaborate with Maimonides Medical Center to investigate the utility of Lymphoseek (technetium Tc 99m tilmanocept) Injection in lymphatic mapping procedures for colorectal cancer. Dr. Danny Sherwinter, surgeon and the Director of the Department of Minimally Invasive & Bariatric Surgery at Maimonides Medical Center in Brooklyn, NY, will lead the investigator-initiated clinical study. This open-label evaluation, expected to start enrollment in early 2013, will be performed at Maimonides and will include the assessment of lymph nodes from up to 40 colon cancer subjects. According to the American Cancer Society, approximately 140,000 new cases of colorectal cancer are expected to be diagnosed in the United States annually¹ while worldwide annual diagnosis is over 1.2 million.²

"While colorectal surgeons have a strong interest in being able to more accurately pinpoint lymph nodes most likely to contain cancer from among the full draining bed of nodes removed during colorectal cancer resection, the field has been awaiting the advent of a suitable lymphatic mapping agent," commented Dr. Sherwinter. "Although efforts are growing in the use of lymph node mapping in colorectal cancer, the poor sensitivity of current agents and techniques has hindered progress in the field. Due to its receptor-targeting properties and strong performance in other malignancies such as breast and melanoma, Lymphoseek holds promise to open new opportunities in the field of lymphatic mapping in colorectal cancer."

Currently, the approach to lymph node assessment in colorectal cancer is to remove the entire lymph node basin during colon resection surgery, resulting in a large number of lymph nodes for pathology analysis. Interest in lymphatic mapping in colorectal cancer is growing however broad application is impeded by limitations in existing technology which have been associated with high false negative rates.³ With results from Phase III studies demonstrating its rapid injection site clearance and retained localization to key predictive lymph nodes, Lymphoseek has performance advantages that may be well suited to lymphatic mapping in settings such as colorectal cancer in an effort to reduce false negative rates and morbidity, and provide improved diagnostic accuracy.

"This study represents an important step forward in advancing Lymphoseek's medical and market potential in additional cancers where lymphatic mapping may be very useful but in which effective technologies haven't been developed," said Mark Pykett, Navidea's President and CEO. "Collaborations such as this, with innovative investigators at leading medical institutions, are part of Navidea's strategy to maximize the potential for Lymphoseek and help patients who might benefit from more precise identification of key predictive lymph nodes that harbor cancer."

About Lymphoseek®

Lymphoseek® (technetium Tc 99m tilmanocept) Injection is a novel, receptor-targeted, small-molecule, investigational radiopharmaceutical used in lymphatic mapping procedures that are performed to help stage cancers such as 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.

Lymphatic mapping is a procedure in which lymph nodes that may contain tumor metastases are identified and biopsied to determine if cancer has spread beyond the primary tumor. Accurate staging of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. According to the American Cancer Society, approximately 229,000 new cases of breast cancer, 76,000 new cases of melanoma and 67,000 new cases of head and neck cancers are expected to be diagnosed in the United States in 2012.

About Lymphatic Mapping

Lymphatic mapping is a procedure designed to guide lymph node dissection and biopsy procedures. It consists of Intraoperative Lymphatic Mapping (ILM) often accompanied by lymphoscintigraphy. Lymphoscintigraphy is an imaging procedure routinely performed pre-operatively to provide guidance on the location of lymph nodes to be biopsied. ILM is a surgical procedure in which lymph nodes draining the area around a tumor are identified and biopsied to determine if cancer has spread to the lymph nodes. These nodes, commonly referred to as "Sentinel Lymph Nodes," are removed and analyzed for the presence of malignant cells. Lymphatic Mapping provides an accurate staging procedure that can help ensure optimal surgical and therapeutic choices, including the avoidance of the morbidity of a complete lymph node dissection for patients in whom the Sentinel Lymph Nodes were found to be free of cancer.

About Navidea

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) 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®, 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 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.

¹ *Cancer Statistics, 2013. CA Cancer J Clin, 2013;63:11–30*

² *Ferlay J et al; "GLOBOCAN 2008: Estimated Incidence, and Mortality and Prevalence Worldwide in 2008." IARC CancerBase No. 10; Lyon, France: International Agency for Research on Cancer; 2010; p1*

³ *Tiffet O et al; "Combining radioisotopic and blue-dye technique does not improve the false-negative rate in sentinel lymph node mapping for colorectal cancer." Dis Colon Rectum. 2007 Jul;50(7):962-70.*

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