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Navidea Biopharmaceuticals Reaches Interim Analysis Point of Phase 3 Head and Neck Cancer Study of Lymphoseek®

– Company to conduct planned interim analysis of available clinical data –

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals today announced that it has accrued sufficient subjects in its NEO3-06 study in patients with head and neck cancer to enable the Company to conduct a pre-planned interim analysis. This Phase 3 trial of Lymphoseek® (technetium Tc 99m tilmanocept) Injection, a novel intraoperative lymphatic mapping (ILM) agent, is designed to demonstrate the performance of Lymphoseek in identifying sentinel lymph nodes in subjects with squamous cell carcinoma on the head or in the mouth. The interim analysis will compare the pathological analysis of the sentinel lymph nodes localized using Lymphoseek with that of all the lymph nodes removed during a full nodal dissection surgery of the head and neck. This full dissection surgery is considered the gold standard for determining the presence and extent of cancer and staging of the disease in such patients. A total of 82 subjects who underwent pre-planned, full dissection surgery were enrolled and represent the interim analysis cohort. Results from the interim statistical analysis and reporting of the findings will be available upon completion of full site and data audits planned for later in 2013.

"We believe this study is unique because it compares Lymphoseek's performance to a pathological '*truth standard*' obtained from a head and neck cancer procedure in which the entire regional lymph node population is removed," commented Fred Cope, Ph.D., Navidea's Senior Vice President of Pharmaceutical Research and Drug Development. "In 2012, positive data from three sites participating in this study were presented at medical meetings by independent investigators characterizing the performance of Lymphoseek at their individual study centers in identifying sentinel lymph nodes in head and neck squamous cell carcinoma. The results appeared very promising. These investigators reported that, for patients accrued up to that date, Lymphoseek had a 0% false negative rate and was 100% predictive of the pathological status of the patient."

Dr. Cope added, "In head and neck cancer it is not uncommon to remove 40, 50, or even 100 regional lymph nodes during full dissection surgery, which can result in substantial and long-term morbidity for patients. An effective sentinel lymph node mapping agent could markedly limit the number of lymph nodes required to conduct pathological assessment and determine whether the cancer has spread. We believe that the NEO03-06 study may provide additional data to demonstrate Lymphoseek's usefulness in characterizing this important type of cancer, and potentially support its use as a sentinel lymph node mapping agent that can facilitate accurate cancer staging and decrease the extent of surgery for some patients, thereby reducing possible serious morbidity."

“This study is part of Navidea’s strategy to expand the utilization of Lymphoseek into multiple cancer types to assist physicians and patients in improving the accuracy of cancer diagnosis and staging,” said Thom Tulip, Ph.D., Executive Vice President and Chief Business Officer. “We believe that Lymphoseek fills an important unmet need as an ideal agent to enable lymphatic mapping in cancers where the procedure may be highly useful, but for which a suitable agent has not yet been developed. Lymphoseek targets key predictive lymph nodes through its specifically-designed, receptor-based mechanism, which we believe can enhance diagnostic accuracy through rapid injection site clearance, stable target binding, and fewer false negative results. We believe these characteristics can enable more accurate staging of cancer in patients undergoing lymphatic mapping procedures, while affording scheduling flexibility.”

About the Lymphoseek NEO3-06 Trial

Navidea’s NEO3-06 clinical trial is an open-label, multicenter study of Lymphoseek® (technetium Tc 99m tilmanocept) Injection. The study is designed to identify Sentinel Lymph Nodes (SLNs) and determine the false negative rate (FNR) associated with Lymphoseek-identified SLNs relative to the pathological status of non-SLNs in head and neck and intraoral squamous cell carcinoma. This study is a supplement to the previously conducted Phase 3 trials of Lymphoseek in breast cancer and melanoma designed to establish Lymphoseek as an effective radiopharmaceutical agent to be used in the intraoperative localization of lymph nodes in the lymphatic pathway draining the primary site of a tumor which have the highest probability of harboring 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.

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