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Meta-analysis of Navidea Biopharmaceuticals Lymphoseek® Phase 3 Data Compared to Standard of Care Techniques Published in Conjunction with the ASCO Annual Meeting

Data from the Phase 3 Clinical Trial for Intraoperative Lymphatic Mapping (ILM) of Lymph Nodes in Breast Cancer Compared to Sulfur Colloid and Vital Blue Dye Reviewed

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that the abstract reviewing a meta-analysis of Phase 3 clinical trial for Intraoperative lymphatic mapping (ILM) of lymph nodes in breast cancer, compared to standard of care techniques has been published in conjunction with the 2012 Annual Meeting of the American Society of Clinical Oncology (ASCO). The abstract entitled, *"The novel receptor targeted (CD206) 99mTc-labeled tilmanocept versus the currently employed Tc99m-sulfur colloid in intraoperative lymphatic mapping (ILM) on key performance metrics in breast cancer"* is published in the *Journal of Clinical Oncology Online 2012; e21066*.

ILM is a critical technique in the assessment and removal of solid tumors, such as a breast cancer, and utilizes the injection of a color agent and/or a radiopharmaceutical imaging agent. These agents are tracked during surgery, either visually or with a gamma-detection probe. ILM is designed to aid the surgeon in identifying lymph nodes that may have a connection to the primary tumor. In the U.S., ILM employs a non-standard radiopharmaceutical agent known as Sulfur-colloid (TcSC) which was recently approved by the FDA for breast cancer ILM based on a literature review. In contrast, Lymphoseek was studied in two prospective Phase 3 trials which compared Lymphoseek to vital blue dye (VBD), the same color agent utilized in the FDA assessment of TcSC.

The comparison of Lymphoseek versus TcSC plus VBD using a meta-analysis and pooled analysis, was based on the TcSC FDA review document, and focused on two functional endpoints. These were the *Localization Rate* which is the percentage of patients with one or more radio-detected nodes and the *Degree of Localization* which is the number of radio-detected nodes per patient. Both of these metrics help define the potential for an imaging agent's performance in ILM and the potential identification of metastasis to other nodes. The Localization Rate for TcSC/VBD was 94% and for Lymphoseek it was significantly greater at 99.91% by meta-analysis and 98.65% by pooled analysis ($p<0.0001$ and $p<0.008$, respectively). The Degree of Localization derived from the publication data base for TcSC was 1.6 nodes per patient and for Lymphoseek it was 2.08 per patient by meta-analysis and

2.16 per patient by pooled analysis ($p<0.0001$ and $p<0.0001$, respectively).

The analysis concluded that, in breast cancer, Lymphoseek provided significantly greater performance over the current ILM standard of care techniques in the key metrics of lymph node localization and identification of the number of lymph nodes found per patient. The data were authored by personnel from Navidea's clinical department and Statking Clinical Data Systems, an independent statistical consulting group from Fairfield, Ohio.

Frederick O. Cope, Ph.D., FACN, CNS, Navidea's Senior Vice President of Pharmaceutical Research and Clinical Development commented, "Further to results reported to the Sentinel Node Oncology Foundation and International Sentinel Lymph Node Working Group earlier this year, we are clarifying that these data represent not only a comparison of Lymphoseek to sulfur colloid but to sulfur colloid plus Vital Blue Dye. The results of this type of statistical evaluation provide a comparison with the current standard of care agents employed in the practice of ILM in breast cancer and indicate Lymphoseek may provide improved diagnostic ILM over the currently employed non-specific radiopharmaceutical lymphatic mapping agents."

Mark Pykett, V.M.D., Ph.D., Navidea's President and CEO said, "We are pleased with opportunity to provide these comparative results derived from our Phase 3 clinical trials. Scientific analysis such as this, in key association meetings with internationally recognized investigators provide opportunities for Navidea to discuss its findings and share key results from its trials. We expect to continue our efforts to provide additional key data to investors over the coming months."

About Lymphoseek

Lymphoseek is a proprietary radioactive tracing agent being developed for use in connection with gamma detection devices in pre-operative lymphoscintigraphy imaging and in a surgical procedure known as ILM. Lymphoseek works by binding to a specific receptor found on the surface of dendritic cells and macrophages, which reside in high concentration in lymph nodes. This receptor-targeted property of Lymphoseek enables it to attach to and remain within lymph nodes.

Two Phase 3 multi-center clinical trials for Lymphoseek in subjects with breast cancer or melanoma have been completed (NEO3-05 and NEO3-09; www.clinicaltrials.gov trial registration numbers NCT00671918 and NCT01106040, respectively). A third Phase 3 clinical study to evaluate the efficacy of Lymphoseek as a sentinel lymph node tracing agent in subjects with head and neck squamous cell carcinoma is currently ongoing (NEO3-06; www.clinicaltrials.gov trial registration number NCT00911326).

About ILM and Lymphoscintigraphy

To date, Lymphoseek is the first and only receptor-targeted agent developed specifically for Intraoperative ILM. ILM is a surgical oncology 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. Lymphoscintigraphy is an imaging procedure routinely performed pre-operatively to provide surgeons with guidance on the relative location of lymph nodes to be biopsied. ILM with a radiopharmaceutical is specifically intended to identify for the surgeon the first lymph node(s) to receive lymphatic flow from the primary tumor site. These "Sentinel

Lymph Nodes" are removed and analyzed for the presence of malignant cells. By identifying the Sentinel Lymph Nodes prior to surgery, a small incision and focused dissection can be used to remove them. This technique 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 Biopharmaceuticals, Inc.

Navidea Biopharmaceuticals, Inc. (NYSE Amex: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. Navidea is actively developing three radiopharmaceutical agent platforms – Lymphoseek®, AZD4694 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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