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Navidea Biopharmaceuticals Announces Presentation of Lymphoseek® Phase 3 Data at Society of Surgical Oncology Meeting

- Data from Ongoing Clinical Trial for Mapping Sentinel Lymph Nodes in Head and Neck Squamous Cell Carcinoma (HNSCC) Presented -

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE Amex: NAVB), a specialty pharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that data from its Phase 3 clinical study investigating 99m-Tc-Tilmanocept (Lymphoseek®) in oral and squamous cell cancers (SCC) were presented as a poster presentation at the *65th Annual Cancer Symposium of the Society of Surgical Oncology (SSO) meeting held in Orlando, Florida, March 21-24, 2012.* The data presented by investigator Stephen Y. Lai, M.D., Ph.D., FACS, of the University of Texas MD Anderson Cancer Center, describe the Center's initial experience with Lymphoseek in Sentinel Lymph Node (SLN) mapping in nine patients with head and neck SCC (HNSCC).

Frederick O. Cope, Ph.D., FACN, Navidea's Senior Vice President of Pharmaceutical Research and Clinical Development commented, "These data comprise the first presentation of Lymphoseek's potential utility in oral cancers. The presentation by Dr. Lai suggests that Lymphoseek's previously reported ability to accurately facilitate identification of primary draining nodes necessary to properly stage patients with breast cancer or melanoma may also apply in patients with HNSCC. We believe this is due to Lymphoseek's rapid transit through lymphatic vessels and targeted binding to the mannose binding receptors (MBR) within key predictive nodes. The results in these nine patients demonstrated a false negative rate of zero, the same as obtained with full nodal dissection. However, using Lymphoseek, substantially fewer lymph nodes are removed than with full nodal dissection. This may enable surgeons to reduce the need for more extensive lymph node dissection, potentially sparing them from the morbidity and side effects of full nodal dissection while not sacrificing accuracy in the detection of key predictive lymph nodes identified by more aggressive full regional dissection."

The ongoing trial (NEO3-06; NCT00911326) is a multicenter, open-label, non-randomized, single arm, within-group trial of Lymphoseek for the detection of tumor-draining Sentinel Lymph Nodes in subjects with known cutaneous or mucosal SCC of the head and neck. All subjects received a single dose of Lymphoseek. The presented data represent the findings from nine subjects who were injected, underwent surgery, and completed a 30-day follow up at MD Anderson. Most subjects were injected on the day prior to their surgical procedure. In the NEO3-06 trial, all subjects received the standard treatment of a full regional nodal

dissection and the results of Lymphoseek-identified nodes were compared to pathology-positive nodes obtained from the full regional nodal dissection. In the nine subjects reported on by Dr. Lai, a total of 360 nodes were excised (22-55 non-SLNs identified per patient, median 39, average 40). The data show preoperative imaging with Lymphoseek provided accurate correlation of lymphatic drainage to tumor-involved anatomic regions and nodes, including SLNs contralateral to (opposite) the primary tumor. The 0% false negative rate (FNR) in this small initial cohort indicates that Lymphoseek accurately identifies those nodes with the highest probability of accurately reflecting the status of regional/cervical metastases (i.e., SLNs). There have been no significant adverse events related to the use of Lymphoseek.

“Patients with HNSCC may have more than one sentinel (or primary drainage) lymph node, and all of these lymph nodes need to be excised and evaluated in order to accurately stage and manage our patients,” said Dr. Lai. “Our initial clinical experience with Lymphoseek demonstrates the utility, diagnostic predictive value, and safety of 99m-Tc-Tilmanocept for both preoperative lymphoscintigraphy and intraoperative localization. The 100% agreement of Sentinel Lymph Node status with the pathology findings in the complete neck dissection supports the efficacy of both Lymphoseek and the Sentinel Lymph Node approach for the care of our patients.”

The results presented by Dr. Lai are interim results from his clinical site’s participation in NEO3-06 that may or may not be consistent with the complete data that will be available when the trial is completed, and the percentage agreement between the nodes identified by Lymphoseek and the pathology results from a complete neck dissection may decline upon analysis of the data from the completed trial.

About Lymphoseek

Lymphoseek is a proprietary radioactive diagnostic tracing agent being developed for use in connection with gamma detection devices in pre-operative lymphoscintigraphy imaging and a surgical procedure known as Intraoperative Lymphatic Mapping. 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 concluded (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 Lymphatic Mapping (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. 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 the node. This technique provides an accurate staging procedure that spares patients who are negative for lymph node metastasis by Sentinel Lymph Nodes sampling the morbidity of a complete lymph node dissection.

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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