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Lymphoseek® Data Presented by Independent Investigators at 8th International Conference on Head and Neck Cancer

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, noted today that individual site, investigator-initiated results of an ongoing Phase 3 clinical trial of 99m-Tc-Tilmanocept (Lymphoseek®) were presented at the American Head and Neck Society's 8th International Conference on Head and Neck Cancer (ICHNC), held in Toronto, July 21-25, 2012. Investigators from the University of Texas MD Anderson Cancer Center, The Ohio State University and the University of Miami reported their personal experiences with the use of Lymphoseek in head and neck squamous cell carcinoma.

"Our initial clinical experience with 99m-Tc-Tilmanocept has demonstrated its utility, diagnostic predictive value and safety in our patients, both preoperatively in lymphoscintigraphy and for intraoperative localization," said Dr. Stephen Y. Lai, M.D., Ph.D., FACS, of the University of Texas MD Anderson Cancer Center. "In determining the extent of early-stage oral cavity squamous cell carcinoma, we are evaluating the efficacy of sentinel lymph node (SLN) biopsy to improve staging and direct treatment of our patients. Many patients have more than one SLN in the head and neck, so the ability of a product such as Lymphoseek to accurately identify and map SLNs can facilitate accurate staging and may potentially decrease some patients' extent of surgery, thus reducing possible serious morbidity."

"The data reported on the performance of Lymphoseek in identifying sentinel lymph nodes in head and neck squamous cell carcinoma at ICHNC from independent site investigators, although not from Navidea, appear promising. We look forward to reviewing the full data sets from these institutions at the appropriate time as part of the customary process of our Phase 3 clinical study," said Fred Cope, Ph.D., Navidea's Senior Vice President of Pharmaceutical Research and Drug Development. "Navidea continues to look forward to the PDUFA date of September 10, 2012, for the use of Lymphoseek in lymphatic mapping in cancer patients. We believe that in comparing Lymphoseek performance to a pathology truth standard, the head and neck Phase 3 study may provide additional data in support of an augmented label for Lymphoseek aimed at sentinel lymph node biopsy."

Highlights of the Presentations

- In an oral presentation, "Use of a Novel Receptor-targeted (CD206) Radiotracer, 99m-Tc-Tilmanocept, and SPECT/CT for Sentinel Lymph Node (SLN) Mapping in Head and Neck Squamous Cell Carcinoma (SSCa): Initial Report of Institutional Experience in an

Ongoing Phase 3 Study (S146)," Dr. Anna Marcinow of The Ohio State University described the clinical experience with 99m-Tc-tilmanocept in 18 patients. As stated in the abstract, "The data yielded a FNR of 0% and a negative predictive value of 100% using 99m-Tc-tilmanocept in conjunction with SLN mapping and biopsy in the identification of occult metastases."

- In a second oral presentation titled, "99m-Tc-Tilmanocept-Identified Sentinel Lymph Nodes Relative to the Pathological Status of Non-Sentinel Lymph Nodes in an Elective Neck Dissection in Cutaneous and Intraoral Head and Neck Squamous Cell Carcinoma: A Single Institutional Experience (S150)," Dr. Stephen Y. Lai, of the University of Texas MD Anderson Cancer Center, described the experience with 99m-Tc-tilmanocept. As stated in the abstract, "Nineteen patients have been enrolled at MD Anderson, and fifteen patients have completed a 30-day follow up at this site which is actively enrolling patients. As all intraoperative 99m-Tc-tilmanocept findings were predictive of the END findings and lead to correct patient staging, the FNR per patients evaluated at this site is 0%. There have been no significant adverse events related to the use of 99m-Tc-tilmanocept."
- The clinical experience at the University of Miami was presented in a poster by its author, Dr. Francisco Civantos, titled "Clinical Experience at the University of Miami in a Phase 3 Trial Using Receptor Targeted 99m-Tc-Tilmanocept to Identify and Evaluate the Pathological Status of Sentinel Lymph Nodes (SLNs) vs. Elective Neck Dissection (END) for Patients with Intraoral Squamous Cell Carcinoma." As stated in the abstract, "At this actively enrolling site, eleven patients have been enrolled. Six patients have undergone SLN mapping and surgery, and completed the study with a 30 day safety follow up. Results showed a 0% per patient FNR, indicating that 99m-Tc-tilmanocept accurately identified those nodes with the highest probability of containing tumor metastases. Additionally, in these patients a negative 99m-Tc-tilmanocept-identified pathology status was 100% predictive of the pathological status of the patient. There have been no significant adverse events related to the use of 99m-Tc-tilmanocept in these patients."

The results presented at ICHNC are independent results from individual clinical sites participating in NEO3-06 that may or may not be consistent with the complete data that will be available when the trial is completed. The percentage agreement between nodes identified by Lymphoseek and 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 tracing agent being developed for use in connection with gamma detection devices in pre-operative lymphoscintigraphy imaging and in a surgical procedure known as Intraoperative Lymphatic Mapping (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 first draining 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 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 MKT: 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.

Navidea Biopharmaceuticals

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