

May 20, 2014



# Navidea Announces Eleven Scientific Presentations of Results from Lymphoseek® and Manocept™ Studies at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that data and results from its Lymphoseek® (technetium Tc 99m tilmanocept) Injection studies in breast cancer, melanoma or head and neck cancer and its Manocept™ studies in Rheumatoid Arthritis and Kaposi Sarcoma are being presented at the Society of Nuclear Medicine and Molecular Imaging Annual Meeting from June 7-14, 2014 in St. Louis, MO. Details of the eleven presentations by Navidea and its collaborators are listed below.

Date: **June 8, 2014**

Poster Title: *Fluorescent CD206-targeted Manocept-Cy3 (Mano-Cy3) specifically localizes on macrophages (MPs) derived from rheumatoid arthritis (RA) patients' synovial fluid & is quantitatively greater than that from non-RA patients.*

Presenter: Wael Jarjour, The Ohio State Univ. Wexner Medical Center, Columbus, OH

Poster Section: **Cardiovascular, Endocrine, Other Posters**

Poster Title: *Intravenous administration (IV) of the CD206-targeted Manocept-Cy3 (Mano-Cy3) to mice with induced rheumatoid arthritis (RA) results in heterogeneous localization of Mano-Cy3 with strong specificity for RA-expressing joints.*

Presenter: Thomas Rosol, The Ohio State University. College of Veterinary Medicine, Columbus, OH

Poster section: **Cardiovascular, Endocrine, Other Posters**

Date: **June 9, 2014**

Poster Title: *CD206-targeted Cy3-Manocept (Mano-Cy3) localizes in nearly all cells present in Kaposi's sarcoma representing an opportunity for dynamic imaging, local staging and a potential for visceral metastasis imaging.*

Presenter: Michael McGrath, AIDS & Cancer Specimen Resource, San Francisco, CA

Poster section: **Sarcoma/Melanoma Posters**

Poster Title: *99mTc-Tilmanocept provides a zero-false negative rate (FNR) and accurate staging when used in ex vivo sentinel node (SLNB) evaluation of a pilot cohort of colorectal cancer patients (CRCP).*

Presenter: Daniel Sherwinter, The Maimonides Medical Center, Brooklyn, NY

Poster section: **GI-Colorectal & Liver Posters**

Poster Title: *CD206 receptor-targeted 99mTc-Tilmanocept is equally effective in detection of sentinel lymph nodes (SLNs) in breast cancer (BC), melanoma (ME), and head/neck squamous cell carcinoma (HNSCC) with ≥99% accuracy.*

Presenter: Michael Blue, Navidea Biopharmaceuticals, Dublin, OH

Poster section: **Head and Neck Posters**

Poster Title: *A 3-year follow-up study of breast cancer (BC) or melanoma (ME) patients (Pts) who underwent sentinel node biopsy (SLNB) indicates a < 2% false negative rate performance with CD206 receptor-targeted 99mTc-tilmanocept as the sole intraoperative lymphatic mapping agent.*

Presenter: Joanna Shuping, Navidea Biopharmaceuticals, Dublin, OH

Poster section: **Breast Cancer Poster Session**

Poster Title: *The use of 99mTc-tilmanocept efficacy for sentinel lymph node biopsy (SLNB) with surgery the same day of injection (SDI) or surgery the day after injection (DAI) does is not different across multiple solid tumors.*

Presenter: David Colborn, Navidea Biopharmaceuticals, Dublin, OH

Poster section: **Head and Neck Posters**

Poster Title: *The high sensitivity (SEN) of 99mTc-Tilmanocept is unaffected by injection route and interval from injection to surgery across solid tumor types [breast cancer (BC), melanoma (ME) & head/neck squamous cell carcinoma (HNSCC)].*

Presenter: Frederick Cope, Navidea Biopharmaceuticals, Dublin, OH

Poster section: **Breast Cancer Poster Session**

Date: **June 10, 2014**

Oral Title: *The CD206-targeted, macrophage (MP)-localizing 99mTc-tilmanocept is accrued ~3-times greater in tumor-positive sentinel lymph nodes (SLNs) than tumor-negative SLNs and 18-times greater than non-SLNs.*

Presenter: Frederick Cope, Navidea Biopharmaceuticals, Dublin, OH

Sc. Paper section: **Head and Neck I**

Date: **June 11, 2014**

Oral Title: *A pooled assessment of 384 patients with breast cancer, melanoma or squamous cell carcinoma of the head/neck (cutaneous and oral) shows a false negative rate for identifying pathology-positive lymph nodes of less than two-percent when CD206 receptor-targeted 99mTc-tilmanocept is used as a single agent.*

Presenter: Bonnie Abbruzzese, Navidea Biopharmaceuticals, Dublin, OH

Sc. Paper  
section: **Sarcoma/Melanoma**

Oral Title: *A pooled assessment of the per patient negative predictive value (NPV; n=286) and positive predictive value (PPV; n=98; based on histological localization) for patients with breast cancer or melanoma or squamous cell carcinoma of the head/neck (cutaneous and oral) shows that no single metric has less than 99-percent performance for CD206-targeted 99mTc-Tilmanocept.*

Presenter: Cornelia Reininger, Navidea Biopharmaceuticals, Dublin, OH

Sc. Paper  
section: **Breast Cancer I**

## About Lymphoseek®

Lymphoseek® (technetium Tc 99m tilmanocept) Injection is a novel, receptor-targeted, small-molecule radiopharmaceutical used in lymphatic mapping procedures that are performed to help in the diagnostic evaluation of potential cancer spread for patients with 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. Lymphoseek was approved by the U.S. Food and Drug Administration in March, 2013 for use in lymphatic mapping to assist in the localization of lymph nodes draining a primary tumor in patients with breast cancer or melanoma. The Company anticipates continuing development of Lymphoseek into other solid tumor areas that may include head and neck cancers, prostate cancer, thyroid cancer, lung/bronchus cancers, colorectal cancer and others. Lymphoseek was granted Fast Track and Priority Review designation for its supplemental new drug application (sNDA) for sentinel lymph node detection in patients with head and neck cancer.

Accurate diagnostic evaluation of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. According to publicly available information, approximately 235,000 new cases of breast cancer, 76,000 new cases of melanoma and 69,500 new cases of head and neck/oral cancer are expected to be diagnosed in the United States in 2014, and approximately 367,000 new cases of breast cancer, 83,000 new cases of melanoma and 137,000 new cases of head and neck/oral cancer diagnosed in Europe annually.

## U.S. Indication and Important Safety Information About Lymphoseek

### **Indication**

Lymphoseek (technetium Tc 99m tilmanocept) Injection is a lymphatic mapping agent indicated for use with a hand-held gamma counter to assist in the localization of lymph nodes draining a primary tumor site in patients with breast cancer or melanoma.

### **Important Safety Information**

In clinical trials with Lymphoseek, no serious hypersensitivity reactions were reported, however Lymphoseek may pose a risk of such reactions due to its chemical similarity to dextran. Serious hypersensitivity reactions have been associated with dextran and modified forms of dextran (such as iron dextran drugs).

Prior to the administration of Lymphoseek, patients should be asked about previous hypersensitivity reactions to drugs, in particular dextran and modified forms of dextran. Resuscitation equipment and trained personnel should be available at the time of Lymphoseek administration, and patients observed for signs or symptoms of hypersensitivity

following injection.

The most common adverse reactions are injection site irritation and/or pain (<1%).

**FULL LYMPHOSEEK PRESCRIBING INFORMATION CAN BE FOUND AT:**

**[WWW.LYMPHOSEEK.COM](http://WWW.LYMPHOSEEK.COM)**

### **About the Manocept™ Platform**

Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on macrophages. Macrophages play important roles in many disease states and are an emerging target in many disorders where diagnostic uncertainty exists. This flexible and versatile platform acts as an engine for purpose-built molecules that may enhance diagnostic accuracy, clinical decision-making and ultimately patient care, while offering the potential to utilize a breadth of diagnostic imaging modalities, including SPECT, PET, intra-operative and/or optical-fluorescence detection. The Company's FDA-approved precision diagnostic lymphatic mapping agent, Lymphoseek® (technetium 99m tilmanocept) Injection, is representative of the ability to successfully exploit this mechanism to develop powerful, new diagnostic agents.

### **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 developing multiple precision diagnostic products and platforms, including NAV4694, NAV5001, Manocept™ and NAV1800 (RIGScan™), to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and, ultimately, patient care. Lymphoseek® (technetium 99m tilmanocept) Injection, Navidea's first commercial product from the Manocept platform, was approved by the FDA in March 2013. 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](http://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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Source: Navidea Biopharmaceuticals, Inc.