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# Navidea Forms Macrophage Therapeutics Business Unit to Explore Therapeutic Applications of Manocept™

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals (NYSE MKT: NAVB) announced today the formation of a new business unit, Macrophage Therapeutics, to further explore therapeutic applications for the Manocept™ platform. The Manocept platform serves as the molecular backbone of Navidea's FDA-approved, activated macrophage-targeting agent, Lymphoseek® (technetium Tc 99m tilmanocept) injection. Preclinical data being developed by the Company using tilmanocept linked to various therapeutic agents suggest that tilmanocept's binding affinity to CD206 receptors demonstrates the potential for this technology to be useful in treating diseases linked to the over-activation of macrophages. This includes various cancers as well as autoimmune, infectious, cardiovascular, and central nervous system diseases.

"Navidea's primary focus remains the successful commercialization of Lymphoseek for use in sentinel lymph node detection and lymphatic mapping," said Rick Gonzalez, Chief Executive Officer of Navidea. "However, given Manocept's potential to be applied in the treatment of multiple diseases based on its unique targeting properties, we have formed this new business unit to pursue therapeutic development. The plan is to continue preclinical research, further assess therapeutic agents that may be paired with Manocept, and evaluate optimal indications and regulatory pathways to enable the most efficient path to market."

Navidea intends to structure Macrophage Therapeutics such that it will remain under Navidea's control enabling existing shareholders to capture potential future value, but also allow funding of future development in a standalone, non-dilutive manner to Navidea's existing shareholders. Current board members Michael M. Goldberg, M.D. and Eric K. Rowinsky, M.D. and Navidea's Chief Scientific Officer, Frederick O. Cope, Ph.D. have been appointed to focus on the launch of the new unit.

"Manocept has a unique and powerful ability to seek out macrophages that are overactive in the body," said Michael Goldberg, M.D. "Linking a radioisotope to illuminate the presence of disease, such as the case with the FDA-approved Lymphoseek, is just the beginning. Manocept may also be combined with well-characterized therapeutic agents designed to destroy unwanted macrophages. Based on preclinical data, we look forward to advancing Manocept-based therapeutics into clinical development."

## **About Macrophage Therapeutics**

Macrophage Therapeutics seeks to leverage Navidea's FDA-approved diagnostic applications and patented Manocept™ platform as a delivery system to target activated macrophages and develop treatments for cancer, cardiovascular, autoimmune, inflammatory, infectious, and CNS diseases. Navidea's Manocept platform is predicated on

the ability to specifically target the CD206 mannose receptor expressed on activated 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 and delivery of therapeutic agents. The Company's FDA-approved precision diagnostic lymphatic mapping agent, Lymphoseek<sup>®</sup> (technetium Tc-99m tilmanocept) injection, is representative of the ability to successfully exploit this mechanism to develop powerful, new diagnostic and therapeutic agents.

### **About Macrophage Therapeutics Oversight Group**

[Michael M. Goldberg, M.D.](#) has been a member of the Navidea Board of Directors since his appointment in November 2013 and is currently a Managing Partner of Montaur Capital Partners. Dr. Goldberg has extensive leadership experience as a chief executive in public biotechnology companies and is highly familiar with the Wall Street investor environment.

[Eric K. Rowinsky, M.D.](#) has served as a director of Navidea since July 2010. He is currently Chief Medical Officer and Head of Research and Development at Stemline Therapeutic, Inc. During his career, Dr. Rowinsky has amassed extensive clinical research and drug development experience, oncology expertise as well as broad scientific and medical knowledge.

[Frederick O. Cope, Ph.D.](#) is Navidea's Senior Vice President and Chief Scientific Officer and has extensive experience in pharmaceutical research and clinical development. He and his team were instrumental in the clinical development programs leading to FDA-approval of Lymphoseek.

### **Lymphoseek<sup>®</sup> Indication and Important Safety Information – U.S.**

Lymphoseek is a radioactive diagnostic agent indicated with or without scintigraphic imaging for:

- Lymphatic mapping using a handheld gamma counter to locate lymph nodes draining a primary tumor site in patients with solid tumors for which this procedure is a component of intraoperative management.
- Guiding sentinel lymph node biopsy using a handheld gamma counter in patients with clinically node negative squamous cell carcinoma of the oral cavity, 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.

Any radiation-emitting product may increase the risk for cancer. Adhere to dose

recommendations and ensure safe handling to minimize the risk for excessive radiation exposure to patients or health care workers. In clinical trials, no patients experienced serious adverse reactions and the most common adverse reactions were injection site irritation and/or pain (<1%).

FULL LYMPHOSEEK PRESCRIBING INFORMATION CAN BE FOUND AT:  
[WWW.LYMPHOSEEK.COM](http://WWW.LYMPHOSEEK.COM)

**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 Manocept™, NAV4694, and NAV5001, to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and, ultimately, patient care. Lymphoseek® (technetium Tc 99m tilmanocept) injection, Navidea's first commercial product from the Manocept platform, was approved by the FDA in March 2013 and by the EMA in November 2014. 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.*

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