

September 25, 2015



Macrophage Therapeutics Produces First Two Immunoconstructs

- Studies to be initiated in a variety of disease models in animals -

DUBLIN, OHIO--(BUSINESS WIRE)-- Macrophage Therapeutics, Inc., a subsidiary of Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAVB), today announces that it has developed a process for producing the first two therapeutic Manocept™ immunoconstructs, MT-1001, designed to specifically target and kill activated CD206+ macrophages and MT-2001, designed to inhibit the inflammatory activity of activated CD206+ macrophages. Activated CD206+ macrophages are implicated in numerous diseases ranging from cancer to autoimmune diseases to CNS diseases like Alzheimer's disease and multiple sclerosis.

MT-1001 and MT-2001 were developed from the Manocept™ platform technology and contain a similar chemical scaffold and targeting moieties designed to selectively target CD206+ macrophages. A payload of a therapeutic molecule is conjugated to each immunoconstruct through a linkage that will release the molecule within the targeted tissue: MT-1001 has doxorubicin, an anthracycline antitumor antibiotic, conjugated to the Manocept backbone and MT-2001 has a potent anti-inflammatory agent conjugated to it. The FDA approved product Lymphoseek® (technetium Tc 99m tilmanocept) injection marketed by Navidea, was developed using the same CD206 targeting technology. Macrophage Therapeutics has contracted with an independent facility to produce sufficient quantities of MT-1001 and MT-2001 along with the concomitant analytical standards, to provide material for planned preclinical animal studies.

In addition, the Company announces the launch of its new web site www.macrophagetcx.com. Visit the new site to learn more about the Manocept platform technology, our scientific trials, study data being generated, and to contact us about potential development and partnering opportunities. We plan to regularly update the website as results are generated

About Lymphoseek®

Lymphoseek® (technetium Tc 99m tilmanocept) injection is the first and only FDA-approved receptor-targeted lymphatic mapping agent. It is a novel, receptor-targeted, small-molecule radiopharmaceutical used in the evaluation of lymphatic basins that may have cancer involvement in patients. Lymphoseek is designed for the precise identification of lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. Lymphoseek is approved by the U.S. Food and Drug Administration (FDA) for use in solid tumor cancers where lymphatic mapping is a component of surgical management and for guiding sentinel lymph node biopsy in patients with clinically node negative breast cancer, melanoma or squamous cell carcinoma of the oral cavity. Lymphoseek has also received European approval in imaging and intraoperative detection of sentinel lymph nodes

in patients with melanoma, breast cancer or localized squamous cell carcinoma of the oral cavity.

Accurate diagnostic evaluation of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. Overall in the U.S., solid tumor cancers may represent up to 1.2 million cases per year. The sentinel node label in the U.S. and Europe may address approximately 235,000 new cases of breast cancer, 76,000 new cases of melanoma and 45,000 new cases of head and neck/oral cancer in the U.S., and approximately 367,000 new cases of breast cancer, 83,000 new cases of melanoma and 55,000 new cases of head and neck/oral cancer diagnosed in Europe annually.

Lymphoseek Indication and Important Safety Information

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

About Macrophage Therapeutics

Macrophage Therapeutics, Inc., a subsidiary of Navidea Biopharmaceuticals, Inc. (NAV), is developing therapeutics using the patented Manocept immunotherapy platform licensed from

Navidea to target over-active macrophages implicated in cancer, cardiovascular, central nervous system, autoimmune, antiviral, and skin diseases. Manocept specifically targets CD206, or the mannose receptor prevalent on over-active macrophages. The technology enables highly specific targeted delivery of active (either existing or yet to be developed) agents that can modulate the activity of over-active macrophages that have been implicated in many diseases. Targeted delivery should significantly enhance a given compound's efficacy and safety.

About Navidea

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a biopharmaceutical company focused on the development and commercialization of precision diagnostics, therapeutics and radiopharmaceutical agents. Navidea is developing multiple precision-targeted products and platforms including Manocept™ and NAV4694 to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making, targeted treatment 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 in Europe in November 2014. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel radiopharmaceutical agents and therapeutics, and advancing the Company's pipeline through 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.

View source version on businesswire.com:

<http://www.businesswire.com/news/home/20150925005134/en/>

Macrophage Therapeutics

James Goldschmidt, Ph.D., 484-225-0341

jgoldschmidt@macrophagetx.com

or

Navidea Biopharmaceuticals

For Investors:

Tom Baker, 617-532-0624

tbaker@navidea.com

or

For Media:

Sharon Correia, 978-655-2686

Associate Director, Corporate Communications

Source: Navidea Biopharmaceuticals, Inc.