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Navidea's Lymphoseek® Receives Positive Opinion in Europe for a New Reduced Mass Vial

- Navidea's European Partner SpePharm AG, an affiliate of Norgine B.V., will distribute Lymphoseek® -

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAVB) has announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has granted a positive opinion for a new Lymphoseek® 50 microgram kit for radiopharmaceutical preparation. Lymphoseek is a medicinal product for diagnostic use only and is indicated in the EU for imaging and intraoperative detection of sentinel lymph nodes draining a primary tumor in adult patients with breast cancer, melanoma, or localized squamous cell carcinoma of the oral cavity.[1] This new Lymphoseek "dose packaging" enables a single injection per patient and is appropriate for the radiopharmaceutical distribution model in Europe.

"This is an important milestone achieved by both Navidea and our partner SpePharm AG and was achieved through great collaboration by both companies," said William J. Regan, Navidea Senior Vice President and Director Navidea UK, Ltd. "We are excited that Lymphoseek, with proven clinical benefits and performance characteristics which may improve the clinical outcomes of oncology patients, will shortly be available throughout Europe. The impact of this new dose packaging will also be important to Lymphoseek distribution as we register in markets throughout the rest of the world."

Peter Stein, Chief Executive Officer, Norgine commented, "As a European specialist pharma company, Norgine is looking forward to making this specialist product available to patients in Europe. The EMA positive opinion on the Lymphoseek reduced mass dose vial will ensure that patients can have their cancer accurately staged with the minimum of potentially disfiguring and disabling surgical intervention."

Lymphoseek is approved in the U.S. by the U.S. Food and Drug Administration (FDA) for use in lymphatic mapping to locate lymph nodes draining a primary tumor site in patients with solid tumors for which this procedure is a component of intraoperative management and for guiding Sentinel Lymph Node Biopsy (SLNB) using a handheld gamma counter in patients with node negative squamous cell carcinoma of the oral cavity, breast cancer or melanoma.

About Lymphoseek®

Lymphoseek (technetium Tc 99m tilmanocept) injection is the first and only FDA- and EMA-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 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 also received EMA European approval in imaging and intraoperative detection of sentinel lymph nodes draining a primary tumor in patients with melanoma, breast cancer or localized squamous cell carcinoma of the oral cavity.

Accurate diagnostic evaluation of cancer is critical, as results guide therapy decisions and determine 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 600,000 new cases of breast cancer, 160,000 new cases of melanoma and 100,000 new cases of head and neck/oral cancer diagnosed annually.

EU Lymphoseek® Indication

Radiolabelled Lymphoseek is indicated for imaging and intraoperative detection of sentinel lymph nodes draining a primary tumour in adult patients with breast cancer, melanoma, or localised squamous cell carcinoma of the oral cavity.

External imaging and intraoperative evaluation may be performed using a gamma detection device.

Important Safety Information about Lymphoseek® for EU patients

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%).

Prescribing information and more information about Lymphoseek for EU patients is available on the EMA website.

For full prescribing information and more information about Lymphoseek for U.S. patients,

please visit: www.lymphoseek.com.

About Norgine

Norgine is a European specialist pharmaceutical company that has been established for over 100 years. In 2015, Norgine's total revenue was EUR 320 million and the company employs over 1,000 people.

Norgine provides expertise and 'know how' in Europe to develop, manufacture and market products that offer real value to healthcare professionals, payers and patients. Norgine's approach and infrastructure is integrated and focused upon ensuring that Norgine wins partnership opportunities for growth.

Norgine is headquartered in the Netherlands and its global operations are based in Amsterdam and in Harefield, UK. Norgine owns a R&D site in Hengoed, Wales and two manufacturing sites, one in Hengoed, Wales and one in Dreux, France.

For more information, please visit www.norgine.com.

In 2012, Norgine established a complementary business Norgine Ventures, supporting innovative healthcare companies through the provision of debt-like financing in Europe and the U.S. For more information, please visit www.norgineventures.com.

About Navidea

Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAVB) is a biopharmaceutical company focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. 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. The development activities of the Manocept immunotherapeutic platform will be conducted by Navidea in conjunction with its subsidiary, Macrophage Therapeutics. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel products 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, our ability to repay our debt, the outcome of the CRG litigation, 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.

Source: Navidea Biopharmaceuticals, Inc.

References

[1] European Medicines Agency LYMPHOSEEK approval 2014. http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002085/human_med_001827.jsp&mid=WC0b01ac05 Accessed 13 September 2016.

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