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Navidea and Norgine Enter European Commercial Partnership for Lymphoseek®; Navidea to Receive $2 Million Upfront Payment

- Strategic partnership provides market development, sales and marketing infrastructure for Lymphoseek expansion into European marketplace –

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) and SpePharm AG (an affiliate of Norgine BV), a European specialist pharmaceutical company with an extensive pan-European presence, today entered into an exclusive sublicense agreement for the commercialization and distribution of Lymphoseek® 250 microgram kit for radiopharmaceutical preparation (tilmanocept) in the European Union. Under the terms of the agreement, Navidea will receive an upfront payment of $2 million and is eligible to receive additional milestone payments up to $5 million, as well as royalties on European net sales.

Lymphoseek is a receptor-targeted, radiopharmaceutical imaging agent approved by the U.S. Food and Drug Administration in 2013 and by the EU in November 2014. Lymphoseek is approved in Europe for imaging and intraoperative detection of sentinel lymph nodes in patients with breast cancer, melanoma, or localized squamous cell carcinoma of the oral cavity. In these procedures, key lymph nodes adjacent to a primary tumor, that may contain tumor metastases, are identified and biopsied to determine if cancer has spread to these lymph nodes.

“Launching Lymphoseek into new global markets is integral to Navidea’s corporate growth strategy. We believe that Norgine’s commercial, medical and development expertise, combined with its well-established infrastructure and strong presence in the European marketplace, make it an ideal commercialization partner to gain country-by-country reimbursement and drive Lymphoseek adoption,” said Rick Gonzalez, President and Chief Executive Officer of Navidea. “We anticipate a successful and mutually-beneficial partnership with Norgine based on synergistic core competencies, our shared vision for value creation and our strong commitment to providing highly-differentiated products that improve the diagnosis and treatment of disease for patients with unmet medical needs.”

“This agreement with Navidea underscores Norgine’s vision to be the partner of choice and facilitates the growth and expansion of our specialist product portfolio to help improve the treatment of patients throughout Europe,” said Peter Stein, Chief Executive Officer of Norgine. “We look forward to fully engaging our sales force to support commercial launch activities in a marketplace requiring a new alternative.”

“Securing a partner with the commitment to market access development was especially important to us since, unlike the United States where institutions typically rely on unit dose distribution of radiopharmaceutical products by specialized radio-pharmacy distributors, institutions in Europe purchase non-radiolabeled material and compound the finished product on-site,” added Mr. Gonzalez “As a specialist pharmaceutical company, Norgine is optimally positioned to interface directly with a targeted surgical oncologist customer base with a dedicated sales force. We expect Norgine to begin market access work immediately in the major markets in Europe with the goal of supporting commercial launch sometime in early 2016.”

Under terms of the exclusive license agreement, Navidea will supply Lymphoseek product to Norgine; however, Navidea will transfer responsibility for regulatory maintenance of the Lymphoseek Marketing Authorization to Norgine. Norgine will also be responsible for pricing, reimbursement, sales, marketing, medical affairs, and regulatory. In connection with entering into the agreement, Navidea will be entitled to an upfront payment of $2 million, milestones totaling up to an additional $5 million, as well as royalties on European net sales. The initial territory covered by the agreement includes all 28 member states of the European Economic Community with the option to expand into additional geographical areas. Additional terms of the agreement were not disclosed.

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.

EU Lymphoseek® 250 micrograms kit for radiopharmaceutical preparation (tilmanocept)

Indication and Important Safety Information

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 & U.S. 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 at: http://ec.europa.eu/health/documents/community-register/html/h955.htm

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. 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 an 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 US. For more information, please visit www.norgineventures.com.

About Navidea Biopharmaceuticals Inc.

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) is a commercial stage precision medicine 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™, NAV4694, and NAV5001,

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 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 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.

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