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Navidea's Commercial Partner, Norgine B.V., Launches LYMPHOSEEK® in Europe

LYMPHOSEEK® Represents Next-Generation Standard of Diagnosis For Sentinel Lymph Node Detection

LYMPHOSEEK® Commercialized in Three Major European Countries

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB) ("Navidea"), a company focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics, today announced that its European commercial partner, SpePharm AG, an affiliate of Norgine, B.V., launched LYMPHOSEEK® (technetium TC 99m tilmanocept), originally developed by Navidea, in Denmark, the Netherlands and the UK.

Navidea entered into an exclusive sublicense agreement with SpePharm, in exchange Navidea received an upfront payment, milestone payments and will receive royalties on all European net sales. The territory covered by the agreement includes all 28 member states of the European Economic Union.

LYMPHOSEEK® is specifically designed to target, bind to and be retained in sentinel lymph nodes, the first lymph node (or group of nodes) to which cancer cells are most likely to spread from a primary tumour. LYMPHOSEEK® has a false negative rate of 2.6% in T1-T4cN0 oral squamous cell carcinoma (OSCC). It detected sentinel lymph nodes in 98% of patients with Tis, Tx or T1-T4cN0 breast cancer and T1-T4cN0 melanoma.

Michael Goldberg, M.D., President and Chief Executive Officer of Navidea, stated, "The commercial launch of tilmanocept is an important revenue provider for Navidea through royalties that boost our ability to progress our Manocept™ platform further not only in diagnostic utility but also advancing therapeutics development. I applaud Norgine in launching tilmanocept's successful commercialization in three European countries. We also look forward to bringing additional value to our shareholders, and to patients, as Norgine strategizes expanding its commercial launch into the remaining European Union countries."

Europe represents a major growth opportunity and medical need due to LYMPHOSEEK®'s ability to identify lymphatic drainage from tumors in the floor of the mouth (underneath the tongue). Currently up to 70-80% of patients with early oral cancer receive elective neck dissection surgery, an expensive procedure which could be avoided by using sentinel lymph node biopsy (SLNB) for staging. In major European markets, 76,917 new cases of head and neck cancer diagnosed in 2014. The European nuclear medicine/radiopharmaceuticals market is expected to reach $1.62 billion by 2020 from $1.09 billion in 2015, growing at a CAGR of 8.2% from 2015 to 2020.

About LYMPHOSEEK®

LYMPHOSEEK® 50 microgram kit for radiopharmaceutical preparation is approved in Europe 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.[2] External imaging and intraoperative evaluation may be performed using a gamma detection device.[2] LYMPHOSEEK® is designed for the precise identification of lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer.

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%).

Please see full Prescribing Information on www.lymphoseek.com for more information.

About Sentinel lymph node biopsy

Sentinel lymph node biopsy (SLNB) is a diagnostic procedure which involves surgical removal of the first lymph node or group of nodes (the sentinel node) which drain directly from the primary cancer site. It is a surgical procedure which requires an overnight stay in hospital and usually has no significant morbidity attached to it.

About Norgine B.V.

Norgine is a leading European specialist pharmaceutical company with a direct commercial presence in all major European markets. In 2016, Norgine's total revenue was EUR 368 million. Norgine employs over 1,000 people across its commercial, development and manufacturing operations and manages all aspects of product development, production, marketing, sale and supply. Norgine specialises in gastroenterology, hepatology, cancer and supportive care.

Norgine is headquartered in the Netherlands. Norgine owns a R&D site in Hengoed, Wales and two manufacturing sites in Hengoed, Wales and Dreux, France.

About Navidea Biopharmaceuticals

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 based on its ManoceptTM platform to enhance patient care by identifying the sites and pathways of disease and enable better diagnostic accuracy, clinical decision-making, and targeted treatment. Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on activated macrophages. The Manocept platform serves as the molecular backbone of Tc 99m tilmanocept, the first product developed and commercialized by Navidea based on the platform. The development activities of the Manocept immunotherapeutic platform are being conducted by Navidea in conjunction with its subsidiary, Macrophage Therapeutics, Inc. 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.

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