April 18, 2022

Navidea Biopharmaceuticals Announces the Regulatory Approval of Lymphoaim in India

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE American: NAVB) (“Navidea” or the “Company”), a company focused on the development of precision immunodiagnostic agents and immunotherapeutics, today announced the regulatory approval of Lymphoaim (“Lymphoseek” in the rest of the world; Tc99m tilmanocept) by the Central Drugs Standard Control Organisation, India.

Tc99m tilmanocept is approved 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. External imaging and intraoperative evaluation may be performed using a gamma detection device. Tc99m tilmanocept is designed for the precise identification of lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer.

Sayre Therapeutics will lead Lymphoaim commercialization efforts in India through a previously announced exclusive license and distribution agreement with Navidea. Sayre Therapeutics specializes in innovative treatment and medical device commercialization in South Asia.

Dr. Michael Rosol, Chief Medical Officer for Navidea, said, “We are delighted that Lymphoaim has received regulatory approval in India and will be available to patients in need.” Dr. Rosol continued, “This will also bring a new revenue stream to the Company to help us advance other pipeline products.”

Mr. Shukrit Sudhir Chimote, Chief Executive Officer for Sayre, said, “Lymphoaim, a radioactive diagnostic agent, would benefit surgeons in guiding sentinel lymph node biopsies. This product fits well with Sayre’s mission of providing novel treatment solutions, and will certainly help boost our presence in the surgical oncology segment.”

About Sayre Therapeutics

Sayre Therapeutics Private Ltd. is South Asia’s integrated platform for disease management backed by a unique distribution and commercialization model for novel and / or differentiated drugs, companion diagnostics, and drug-delivery devices in the super-specialty areas of Oncology and Immunology.

About Navidea

Navidea Biopharmaceuticals, Inc. (NYSE American: NAVB) is a biopharmaceutical company focused on the development of precision immunodiagnostic agents and immunotherapeutics.

Navidea is developing multiple precision-targeted products based on its Manocept™ 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 Tc99m tilmanocept, the first product developed and commercialized by Navidea based on the platform. 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.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. Forward-looking statements include our expectations regarding pending litigation and other matters. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: our history of operating losses and uncertainty of future profitability; the final outcome of any pending litigation; our ability to successfully complete research and further development of our drug candidates; the timing, cost and uncertainty of obtaining regulatory approvals of our drug candidates; our ability to successfully commercialize our drug candidates; dependence on royalties and grant revenue; our ability to implement our growth strategy; anticipated trends in our business; our limited product line and distribution channels; advances in technologies and development of new competitive products; our ability to comply with the NYSE American continued listing standards; our ability to maintain effective internal control over financial reporting; the impact of the current coronavirus pandemic; and other risk factors detailed in our most recent Annual Report on Form 10-K and other SEC filings. You are urged to carefully review and consider the disclosures found in our SEC filings, which are available at http://www.sec.gov or at http://ir.navidea.com.

Investors are urged to consider statements that include the words "will," "may," "could," "should," "plan," "continue," "designed," "goal," "forecast," "future," "believe," "intend," "expect," "anticipate," "estimate," "project," and similar expressions, as well as the negatives of those words or other comparable words, to be uncertain forward-looking statements.

You are cautioned not to place undue reliance on any forward-looking statements, any of which could turn out to be incorrect. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this report. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements.

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