June 24, 2019

Navidea Biopharmaceuticals Announces SNMMI Press Release and Recognition of Phase 1/2 Study Results

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, is pleased to announce that the results of the Company’s NAV3-21 clinical study at the Society of Nuclear Medicine and Molecular Imaging (“SNMMI”) Annual Meeting in Anaheim, CA have been highlighted with a press release by the SNMMI (http://www.snmmi.org/NewsPublications/NewsDetail.aspx?ItemNumber=31987). The presentation, titled “A Phase I/Phase II Study of Intravenously (“IV”) Administered Tc99m Tilmanocept (“TCT”) to Determine Safety, Tolerability, Optimal Clinical Dose Selection, and Imaging Timepoint in Patients Clinically Diagnosed with Rheumatoid Arthritis (“RA”)" was delivered at the Society’s Annual Meeting on Sunday, June 23, 2019 by Arash Kardan, M.D. In addition, an abstract of the presentation will be published in a future edition of the *Journal of Nuclear Medicine*.

The NAV3-21 study enrolled subjects with active, moderate-to-severe RA, and healthy controls. Results from the completed trial demonstrate that Tc99m tilmanocept is well-tolerated with no serious adverse events, adverse drug reactions, or drug-related adverse events observed. Additionally, static planar images revealed joint-specific Tc99m tilmanocept localization in RA subjects to disease-involved joints of the shoulders, knees, hands, and feet, but no joint-specific localization in healthy control subjects, revealing potentially significant immunodiagnostic information about CD206-expressing synovial macrophage involvement in RA. An optimal imaging time window post-Tc99m tilmanocept IV administration, as well as optimal dosing, were also determined.

Michael Rosol, Chief Medical Officer for Navidea, said, “We are delighted by the recognition of the importance of our Phase 1/2 study results by the SNMMI. In this work we have shown that intravenous administration of Tc99m tilmanocept had no adverse safety signals and that it localizes specifically to joints of patients with active RA and not to those of healthy controls. These results were fundamental to moving forward with our planned Phase 2B and Phase 3 studies and our planned eventual submission to FDA for registration for indications in RA.” Dr. Rosol continued, “This press release and highlight by the SNMMI is the type of external validation of our work that reflects the great medical need for a robust, objective, noninvasive means of assessing inflammation in RA-involved joints. It is our expectation that Tc99m tilmanocept can address this need and provide critical information for rheumatologists to put their patients on the correct therapeutic pathway earlier than is currently possible.”

RA is a chronic disease affecting over 1.3 million Americans and as much as 1% of the worldwide population.[1] If the product is successfully developed, Navidea would expect to

play a major role in the management of RA patients worldwide.

Reference

1. https://www.rheumatoidarthritis.org/ra/facts-and-statistics/

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 for the use of proceeds received from the offering. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: market and other conditions, the satisfaction of customary closing conditions related to the public offering and the impact of general economic, industry or political conditions in the United States or internationally, any future actions by Platinum-Montaur; general economic and business conditions, both nationally and in our markets; our history of 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; our expectations and estimates concerning future financial performance, financing plans and the impact of competition; our ability to raise capital sufficient to fund our development and commercialization programs; our ability to implement our growth strategy; anticipated trends in our business; advances in technologies; our ability to comply with the NYSE American continued listing standards; our ability to maintain effective internal control over financial reporting; 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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Source: Navidea Biopharmaceuticals, Inc.