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Navidea Biopharmaceuticals Data to be Presented at Society of Nuclear Medicine and Molecular Imaging Annual Meeting

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 that Arash Kardan, M.D., will give an oral presentation on the results of the Company's NAV3-21 clinical study at the Society of Nuclear Medicine and Molecular Imaging ("SNMMI") Annual Meeting in June 2019. The presentation is 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")." In addition, an abstract of the presentation will be published in the *Journal of Nuclear Medicine*.

The NAV3-21 study enrolled subjects with active, moderate-to-severe RA and healthy controls. Images were acquired one hour and three hours post-injection of Tc99m tilmanocept. 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. Enhanced anatomic delineation in tilmanocept-positive joints of RA patients was noted via IV administration in this trial when compared to subcutaneous administration of Tc99m tilmanocept studied in a previously-completed Phase 1 trial.

Michael Rosol, Chief Medical Officer for Navidea, said, "Using noninvasive planar imaging and SPECT/CT with Tc99m tilmanocept we can, for the first time, objectively visualize and directly quantify RA disease activity and evaluate joint-specific inflammation. This could also enable noninvasive characterization of joint-level pathobiology and individualization of treatment." Dr. Rosol continued, "The results from this and our previously completed RA trial support our initiative for follow-on Phase 2b and Phase 3 studies intended to garner FDA approval of new indications for Tc99m tilmanocept in RA patients."

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.

Additional information can be found at http://www.snmmi.org/AM/

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. 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.

Forward-Looking Statements

This release and any oral statements made with respect to the information contained in this 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. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: 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 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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