

June 17, 2019



## **Navidea Biopharmaceuticals Announces Day and Time of SNMMI Presentation of Phase 1/2 Study Results and Enrollment Update on its Phase 2B Study**

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 the details of 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 Anaheim, CA. 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")" will be delivered at 12:30 PM, 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.

Navidea's Phase 2B study, titled "Evaluation of the Precision and Sensitivity of Tilmanocept Uptake Value ("TUV") on Tc 99m Tilmanocept Planar Imaging" is ongoing. Two sites are now open for recruitment and the first four patients have been enrolled into the study. It is anticipated that two more sites will be opened shortly. This study is designed to evaluate the reliability and sensitivity of assessments in both healthy controls and in subjects with active RA. The study is stratified into three arms, with the first two arms consisting of [1] disease-free healthy controls and [2] clinically diagnosed RA subjects on stable treatment. The third arm is designed to assess the efficacy of TUV global in clinically diagnosed subjects with active RA and will power the upcoming pivotal Phase 3 trial.

Michael Rosol, Chief Medical Officer for Navidea, said, "We are excited to present the results from our Phase 1/2 study demonstrating joint-specific localization to inflamed joints of RA subjects when compared to healthy controls, as well as determining the optimum clinical dose for imaging with Tc99m tilmanocept in RA." Dr. Rosol continued, "These results have

provided support to our initiative for the currently running follow-on Phase 2B, as well as our next upcoming Phase 2B and the Phase 3 study intended to garner FDA approval of new indications for Tc99m tilmanocept in RA patients. We are very pleased that enrollment of our first Phase 2B has begun and is proceeding well.”

Bonnie Abbruzzese, Navidea’s Senior Director, Clinical Research, said, “We are pleased that subject recruitment for our Phase 2B has started off at a good pace, and the entire clinical team is working hard to continue to open additional sites as well as to monitor continued subject recruitment. The study results to be presented at SNMMI laid the groundwork for this latest trial, and we are looking forward to seeing the results presented in Anaheim.”

RA is a chronic disease affecting over 1.3 million Americans and as much as 1% of the worldwide population.<sup>1</sup> 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](http://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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