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Navidea Biopharmaceuticals Announces Positive Results Encompassing Additional Patients From Its Ongoing Phase 2B Study in Rheumatoid Arthritis

Data Support Hypothesis that Tc99m Tilmanocept Imaging Can Provide Early Indicator of Treatment Response

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 positive results from analysis of subjects who have completed Arm 3 of the Company's ongoing NAV3-31 Phase 2B study. These data further corroborate Navidea's hypotheses that Tc99m tilmanocept imaging can provide robust, quantitative imaging in patients with active rheumatoid arthritis ("RA") and that this imaging can provide an early indicator of treatment efficacy.

Navidea's NAV3-31 Phase 2B trial titled "Evaluation of the Precision and Sensitivity of Tilmanocept Uptake Value (TUV) on Tc99m Tilmanocept Planar Imaging" has three arms: Arm 1 consists of healthy subjects, Arm 2 is comprised of patients with active, moderate-to-severe RA who are on stable therapy, and Arm 3 is a pilot arm of the upcoming Phase 3 trial assessing the ability of Tc99m tilmanocept to provide an early indicator of efficacy of anti-tumor necrosis factor ("TNF") alpha treatment in RA patients.

This third arm was designed in order to evaluate the magnitude of change of Tc99m tilmanocept signal localized to RA-involved joints in patients before and after treatment with an anti-TNF alpha therapy as well as to examine whether the localization or change in localization can serve as an early, quantifiable predictor of treatment efficacy as determined by clinical assessments at 12 and 24 weeks.

A total of 16 subjects with active moderate-to-severe RA were included in this analysis, each of whom was set to begin a new or first-time treatment regimen with an anti-TNF alpha therapy. Whole body and hand/wrist planar gamma camera images were obtained at baseline prior to initiation of new treatment, again at 5 weeks post therapy initiation, and then again at 12 and 24 weeks. A panel of established clinical assessments was performed at each time point as well. Results of the preliminary analysis demonstrate:

- Tc99m tilmanocept imaging from baseline to week 5 was predictive of clinical outcome at 24 weeks in 13 out of 16 patients (81.3%).
- In this dataset, change from baseline to week 5 in Tc99m tilmanocept imaging had high positive and negative predictive value (PPV and NPV, respectively) for clinical outcome

at both 12 and 24 weeks: week 12- PPV= 100%, NPV= 83% and week 24- PPV= 100%, NPV= 77%. These preliminary results indicate that marked changes in Tc99m tilmanocept global uptake values by week 5 are in good agreement with clinical efficacy evaluations made at weeks 12 and 24 of treatment.
- Early results also support the hypothesis that, in a subset of RA patients, the baseline scan alone can be a reliable predictor of non-responsiveness to anti-TNF alpha therapy.

These data continue to support Navidea's hypothesis that Tc99m tilmanocept imaging can provide quantifiable imaging assessment of RA-involved joints that enables early prediction of clinical response.

Michael Rosol, Chief Medical Officer for Navidea, said, "The ongoing analysis of our Phase 2B trial now includes patients followed for up to six months after beginning anti-TNF alpha therapy, and provides us with more evidence that we can objectively predict treatment response early and with a high level of accuracy." Dr. Rosol continued, "We are excited that we are on track to possibly providing rheumatologists and those suffering with RA a noninvasive, quantifiable, early indicator of whether or not an anti-TNF alpha treatment is working. This could bring enormous benefit to these patients by assisting physicians in putting them on the right course of treatment earlier than would otherwise be possible today."

Jed Latkin, Navidea's Chief Executive Officer, said, "The data shared today once again demonstrate the power of Tilmanocept to aid in rheumatology treatment decisions and ultimately improve the course of care for the millions of people across the globe suffering from RA." Mr. Latkin continued, "We are encouraged that data from patients who have completed Arm 3 has continued to support our hypothesis, particularly as the study design of Arm 3 will mirror our upcoming pivotal Phase 3 RA trial."

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 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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