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Navidea Biopharmaceuticals Announces Full Enrollment in its Ongoing Phase 2B Trial of Tc99m Tilmanocept in Rheumatoid Arthritis (RA)

DUBLIN, OH, June 15, 2020 (GLOBE NEWSWIRE) -- 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 full enrollment in its ongoing NAV3-31 Phase 2B study titled "Evaluation of the Precision and Sensitivity of Tilmanocept Uptake Value (TUV) on Tc99m Tilmanocept Planar Imaging". All of the subjects have been enrolled in the three-arm trial, and the study is on track for the last patient to be screened, and evaluated by end of 2020.

The aim of this Phase 2B study is to evaluate the repeatability, reproducibility, and stability of Tc99m tilmanocept imaging in both healthy subjects (Arm 1) and in patients with active RA (Arm 2), as well as to assess the ability of Tc99m tilmanocept to provide an early indicator of efficacy of anti-tumor necrosis factor ("TNF") alpha treatment in RA patients (Arm 3). The third arm mirrors Navidea's Phase 3 study, which has been designed to provide data to understand the magnitude of the signal change that could potentially occur as patients receive therapy. Navidea has enrolled 38 subjects in each Arm (1 and 2), and has concluded with another 29 subjects in Arm 3. Subjects in Arm 3 will be followed up to a period of 24 weeks with regular imaging of Tc99m tilmanocept and clinical assessments at predetermined intervals from time of initiation of anti-TNF alpha.

Interim results previously announced in this trial have provided supportive evidence for Navidea's hypotheses that Tc99m tilmanocept imaging can potentially provide a robust, quantifiable imaging assessment of RA-involved joints that enable the early prediction for physicians to confirm the appropriate clinical response. Navidea remains on track to meet with the FDA to finalize the Phase 3 study design, and the Phase 2B trial will continue in parallel until completion.

Michael Rosol, Chief Medical Officer for Navidea, said, "We are pleased that we were able to fully enroll the required patients in this trial and are on schedule through the current situation with COVID-19. I give full credit to everyone involved in this study for their accomplishments. The enrollment to date gives us encouragement that we will be able to hit the ground running with our planned Phase 3 study later this year." Dr. Rosol continued, "As I have said before, we are excited that we are on track to potentially provide rheumatologists and those suffering with RA with 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, "I am encouraged by the positive feedback we have been given by the physicians and collaborators involved in this transformational Phase 2B trial. We look forward to leveraging the momentum we have generated with NAV3-31 toward our planned NAV3-33 Phase 3 trial later this year."

RA is a chronic disease affecting over 1.3 million Americans and as much as 1% of the worldwide population1. 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 our current studies and potential results, FDA approval process, ability to provide rheumatologists and those suffering from RA with expected benefits, the accuracy and timing of our imaging as an indication of treatment effectiveness, the use of our imaging as part of treatment for RA patients, our ability to progress into a Phase 3 study, our ability to successfully develop products, and the role of Navidea in the management of RA worldwide. 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.

References and links to websites have been provided as a convenience, and the information contained on such websites is not incorporated by reference into this press release. Navidea is not responsible for the contents of third-party websites.

Contact

Navidea Biopharmaceuticals, Inc.
Jed Latkin, CEO
614-973-7490
jlatkin@navidea.com

PCG Advisory, Inc.
Adam Holdsworth
646-862-4607
adamh@pcgadvisory.com

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