

July 3, 2024



Navidea Biopharmaceuticals, Inc. Announces Results of Exploratory Analysis Completed on July 2, 2024

Navidea Biopharmaceuticals, Inc. has completed an exploratory analysis of its Rheumatoid Arthritis Program

COLUMBUS, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (OTC: NAVB) ("Navidea" or the "Company"), a company focused on the development of precision immunodiagnostic agents and immunotherapeutics, today announced disappointing results of an exploratory analysis conducted on the Company's pivotal NAV3-33 clinical trial titled "Evaluation of Tc 99m Tilmanocept Imaging for the Early Prediction of Anti-TNF α Therapy Response in Patients with Moderate to Severe Active Rheumatoid Arthritis (RA)" (ClinicalTrials.gov Identifier: NCT05246280) the "RA Trial."

The purpose of the exploratory analysis was to optimize the diagnostic performance in support of the methodologies to be applied in the final pivotal trial. The results confirm that intravenous Tc 99m tilmanocept can target and produce reliable images of macrophage activity in RA patients, but that these images do not adequately predict which patients will respond to treatment with an anti-TNF alpha medication.

"We were very surprised and disappointed that the results of the exploratory analysis did not support the hypothesis of an overall accuracy of early treatment response approaching 90%, but rather, the overall accuracy of early treatment response was on average consistently below 70%," said Dr. Michael Blue, Navidea's Chief Medical Officer. "Results with that predictive value are not indicative of a commercially viable product."

Given these results, Navidea is suspending all activities related to the RA Trial. The Company is pivoting to focus on exploring all opportunities related to the Company's therapeutic assets.

About Navidea

Navidea Biopharmaceuticals, Inc. (OTC: 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, 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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