July 15, 2021

Navidea Biopharmaceuticals Announces End-of-Phase 2 Type B Meeting Request Granted by the FDA to Discuss Ongoing Clinical Program in Rheumatoid Arthritis

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 the U.S. Food and Drug Administration ("FDA") has granted the Company's request for an End-of-Phase 2 Type B meeting to discuss its ongoing program in Rheumatoid Arthritis ("RA") and advancement to the pivotal Phase 3 trial. The meeting will take place on September 1, 2021, via conference call.

The meeting with the FDA will be centered on discussion of the results from the Company's completed Phase 2b NAV3-31 study, "Evaluation of the Precision and Sensitivity of Tilmanocept Uptake Value (TUV) on Tc99m Tilmanocept Planar Imaging" and the proposed protocol and analysis plans for the Phase 3 trial. Previously, the FDA reviewed the interim data and provided pertinent feedback on progressing the remaining patient data and encouraged an End-of-Phase 2 meeting when complete.

Navidea's NAV3-31 trial had three arms: Arm 1 consisted of healthy subjects, Arm 2 was comprised of patients with active, moderate-to-severe RA who are on stable therapy, and Arm 3 was a pilot arm designed to assess the ability of Tc99m tilmanocept to provide an early indicator of efficacy of anti-tumor necrosis factor ("TNF") α treatment in RA patients. Previously reported interim analyses demonstrated results in support of Navidea's hypotheses that Tc99m tilmanocept imaging can provide robust, quantitative imaging in healthy controls and in patients with active RA, and that this imaging can provide an early indicator of treatment efficacy in patients with active RA.

The pivotal Phase 3 trial will establish the ability of Tc99m tilmanocept imaging to serve as an early predictor of treatment response in RA patients switching to an anti-TNFα therapy. The design and planned conduct of the Phase 3 trial is built upon insights and data from the completed Phase 2b NAV3-31 trial.

Dr. Michael Rosol, Chief Medical Officer for Navidea, said, "We are eager to discuss the results from our completed Phase 2b trial as well as the design of the planned Phase 3 trial with the FDA. Throughout our RA program development, we have worked closely with expert rheumatologists, nuclear medicine specialists, and the FDA itself, and we believe we are on the right path to bringing a valuable tool to bear to meet a large unmet medical need in patients with RA." Dr. Rosol continued, "Success would mean that we can provide rheumatologists and those suffering with RA a noninvasive, quantifiable, early indicator of

whether or not an anti-TNFα 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 is possible today."

Jed Latkin, Chief Executive Officer and Chief Financial Officer for Navidea, said, "We are very excited to meet with the FDA and finally proceed with launching the Phase 3 trial for the approval of Navidea's RA monitoring agent. The clinical and regulatory teams have been working non-stop to complete the review of a massive amount of data obtained from NAV3-31. I am extremely proud of the work they have accomplished to date and eagerly anticipate the next steps towards approval."

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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Source: Navidea Biopharmaceuticals, Inc.