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Navidea Biopharmaceuticals Provides Statement Regarding COVID-19 Pandemic

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, announces the following statement regarding the impact of the COVID-19 pandemic on the company's ongoing clinical development efforts:

First, we would like to express our sincerest gratitude for all of the healthcare workers and other responders on the frontlines who are working tirelessly to combat this global pandemic. This has affected us all. We wanted to share Navidea's response during this time of crisis and provide an update on our research and development activities.

Rheumatoid Arthritis (RA) Diagnosis and Monitoring

Navidea is on track to deliver interim data from arm 3 of the Company's Phase 2b clinical trial (NAV3-31) in the timeframe previously communicated on the March 11, 2020 quarterly update call. Navidea has enrolled sufficient patients to meet these previously communicated timelines.

In regards to the Company's planned meeting with the FDA, management has made no changes to its internal forecast of an FDA meeting in late 2Q/early 3Q 2020. Management believes that sufficient patients have been enrolled to maintain the previous forecast.

The NAV3-33 trial, pivotal Phase 3 trial for rheumatoid arthritis, remains on track for a second-half 2020 launch. This goal echoes guidance previously provided on the March 11, 2020 quarterly update call.

Jed Latkin, Chief Executive Officer of Navidea, said, "Our primary focus is the safety of our Navidea employees, the employees of our clinical trial sites, and the patients in our trials. We are taking every necessary precaution to both mitigate any safety risk along with any long-term impact on our clinical development programs. To date, we have seen no appreciable impact to our RA clinical development and regulatory timelines from COVID-19."

Cardiovascular Disease

Analysis of the data from the Company's Cardiovascular Phase 2b study remains on track. Results provided to Navidea thus far have paralleled data in our earlier published article. These data are supportive of Navidea's hypothesis that Tilmanocept can provide marked signal to background in a host of cardiovascular disease applications. Navidea continues to anticipate meeting with the FDA in the coming months to discuss upcoming clinical trial designs.

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 release and any oral statements made with respect to the information contained in this 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. 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, accumulated deficit, future capital needs, the outcome of any pending litigation, uncertainty of capital funding, dependence on royalties and grant revenue, limited product line and distribution channels, competition, risks of development of new products, our ability to maintain effective control over financial reporting, our ability to comply with NYSE American continued listing standards, the impact of the recent 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 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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