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Navidea Biopharmaceuticals Announces First 110 Subjects Imaged in NAV3-35 Normative Database Phase 2b Study to Support Rheumatoid Arthritis Indications

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 over 110 subjects have been enrolled and imaged in its NAV3-35 Phase 2b study, “Development of a Normative Database for Rheumatoid Arthritis (RA) Imaging with Tc99m Tilmanocept.” Expected total enrollment for this two-arm trial will be 135 participants.

NAV3-35 will establish a database of hand and wrist images taken following Tc99m tilmanocept administration in healthy volunteers age- and sex-matched to the population of RA patients. Tc99m tilmanocept attaches to mannose receptors (CD206) on macrophages that are frequently involved in RA joint inflammation. Relatively smaller numbers of CD206 expressing macrophages normally reside in the joints of healthy people without RA. An integral part of the ability to quantitatively discriminate RA-inflamed joints from those that do not have inflammation using Tc99m tilmanocept imaging is the knowledge of the distribution of Tc99m tilmanocept localization in healthy joints. The establishment of this normal subject database (i.e., normative database) will enable improved accuracy of discrimination of RA-involved joints from non-RA inflamed joints and should have a positive impact on the ability to predict treatment response early. This database will also be used in the training of automated image analysis algorithms to further improve the accuracy of the quantification of Tc99m tilmanocept localization in joints as well as the workflow for later commercialization in RA.

The aim is to recruit 135 volunteers in this two-arm study. The first arm is comprised of 120 healthy subjects who will have planar imaging of their hands and wrists post administration of Tc99m tilmanocept, and arm two is a 15-subject arm comprised of 10 patients with RA and 5 healthy volunteers with the aim of demonstrating the feasibility of 3-dimensional SPECT/CT imaging for the quantitative assessment of RA-involved inflammation in joints. To date, over 100 subjects have been imaged for Arm 1, and 10 in Arm 2.

Dr. Michael Rosol, Chief Medical Officer for Navidea, said, “The normative database, establishing the parameters of what a normal joint looks like with Tc99m tilmanocept, will play an essential part in both the Phase 3 data analysis as well as planned commercial product.” Dr. Rosol continued, “These data will also be used to optimize automated image analysis to improve upon accuracy and streamline workflow for widespread adoption of Tc99m tilmanocept imaging in RA.”

Jed Latkin, Chief Executive Officer and Chief Financial Officer for Navidea, said, “The rapid enrollment of this trial is truly a testament to Navidea’s focus on delivering quick results as we launch more trials to bring the Company ever closer to the launching of the RA Diagnostic product.”

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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