April 8, 2019

Navidea Biopharmaceuticals Receives FDA Feedback Regarding Rheumatoid Arthritis Clinical Trial Design and Provides Business Updates

Company Will Host Conference Call at 5:00 p.m. (ET) on Monday, April 8, 2019

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 it received feedback from the U.S Food and Drug Administration ("FDA") regarding the Company's planned clinical studies that will evaluate joint disease in patients with Rheumatoid Arthritis ("RA") and monitor patient response to therapy.

Clinical Studies in Rheumatoid Arthritis

The Company's proposed RA studies were discussed with the FDA during an in-person meeting, and through follow-up collaborative efforts. The FDA has communicated that the first study, a Phase 2b trial, is aligned with expectations for the studies and that they will continue to work with Navidea as we progress into Phase 3 clinical trials. The Company is now prepared to initiate this study, NAV3-31 (Evaluation of the Precision and Sensitivity of Tilmanocept Uptake Value ("TUV") on Tc99m Tilmanocept Planar Imaging). This study will also provide confirmatory support necessary to initiate Navidea's Phase 3 study program which was also presented to the FDA. The pivotal Phase 3 study program will assess joint disease status and monitor patient response to therapy.

Dr. Michael Rosol, Chief Medical Officer of Navidea, said, "We are delighted to have received the news from the FDA that we are progressing in the right direction with our upcoming Phase 2b study. This study is designed to enable us to establish objective, quantifiable Tc99m tilmanocept imaging metrics of the joints of healthy subjects and patients with active RA. The robust establishment of the range of TUVs from healthy subjects and RA patients is a critical step to set us up for the greater validation of our imaging readout as an early biomarker of patient response to therapy, method for longitudinal monitoring of treatment, and potentially for RA pathobiology subtype discrimination. Our entire clinical team has been pushing hard in preparation and this important trial is set to begin in the near future. We plan to proceed with our timelines and will ensure we remain in line with FDA requirements."

Bonnie Abbruzzese, Navidea's Senior Director of Clinical Development, stated, "We have identified our clinical trial study centers and have received Investigational Review Board approval for the NAV3-31 image stability and outcome trial, which will generate data to guide the development of the pivotal Phase 3 trial. Our investigators are eager to begin enrolling into the NAV3-31 protocol and we expect to inject the first subject this quarter."

Bill Regan, Chief Compliance Officer of Navidea, said, "As we work towards full development of the RA program it is extremely important to work collaboratively with the FDA to ensure continued alignment with FDA expectations in order to achieve the Navidea goal of a successful Phase 3 program to develop the premiere diagnostic agent for patients with RA. Input from the FDA up to this point has been very beneficial and we look forward to continued collaboration as we progress through the complete development program."

Jed Latkin, Navidea's Chief Executive Officer, commented, "This is an important step along the path to approval of our RA diagnostic product candidate and represents Navidea's continued dedication to the execution of our goals and to enhance value for stockholders. We will continue to work with the FDA as data from NAV3-31 becomes available. We will also continue to be transparent with the market and give updates to our stockholders and all interested parties, as appropriate."

RA is a chronic disease affecting over 1.3 million Americans and as much as one percent of the worldwide population.[1] Tc99m Tilmanocept may enable, for the first time, objective visualization and direct quantification of RA disease activity and evaluation of joint-specific inflammation. 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/

Receipt of NYSE American Deficiency Letter

Navidea also announced today that it received a notification (the "NYSE Letter") from the NYSE American LLC (the "NYSE American") stating that Navidea was not in compliance with Section 1003(a)(i) of the NYSE American Company Guide, which requires an issuer to have stockholders' equity of $2.0 million or more if it has reported losses from continuing operations and/or net losses in two of its three most recent fiscal years. The NYSE Letter noted that Navidea's most recent Form 10-K reported stockholders' equity of $1.7 million as of December 31, 2018, and that Navidea has reported losses from continuing operations and/or net losses in its five most recent fiscal years ended December 31, 2018.

Navidea previously disclosed, among other things, that it received a notification from the NYSE American stating that Navidea was not in compliance with Section 1003(f)(v) of the NYSE American Company Guide, which relates to the selling price per share of the Company's securities. The NYSE American staff initially granted Navidea a plan period through February 14, 2019 to regain compliance with Section 1003(f)(v) by effecting a reverse stock split or otherwise demonstrating sustained price improvement. In January 2019, the NYSE American granted the Company an extension until March 31, 2019 to regain compliance with Section 1003(f)(v) of the NYSE American's continued listing standards, and on March 22, 2019 Navidea announced that it was in discussions with the NYSE American regarding the timing of a potential reverse stock split later than March 31, 2019. The NYSE Letter advised that the Company must provide the NYSE American with a plan to regain compliance with the price standard by April 15, 2019 in order to be considered for continued trading through its equity plan period end date of February 14, 2020, subject to periodic review of progress consistent with the equity plan.

In August 2018, Navidea's stockholders voted to approve a potential amendment to the Company's amended and restated certificate of incorporation to effect a reverse split of the Company's common stock, as determined by the Board of Directors at its discretion, of a ratio of not less than one-for-five and not more than one-for-twenty. In addition to the goal to regain compliance of the listing standards, the Company believes that if the reverse split is effected, a higher share price may attract additional brokerage firms and institutional investors who previously may have been prohibited from investing in shares of the Company.

Navidea's Common Stock will continue to be listed on the NYSE American while it attempts to regain compliance with the listing standards noted, subject to Navidea's compliance with other continued listing requirements.

Conference Call Details

Investors and the public are invited to dial-in to a conference call to discuss these business updates through the information listed below, or participate via the audio webcast on the company website. Participants who would like to ask questions during the question and answer session will be prompted by the moderator, who will provide instructions.

Event:	FDA Feedback on Rheumatoid Arthritis Trials; Other Business Updates
Date:	Monday, April 8, 2019
Time:	5:00 pm (Eastern Time)
U.S. & Canada Dial-in:	877-407-0312
Conference ID:	13689696
Webcast Link:	https://webcasts.eqs.com/navidbioph20190408

The recorded conference call can be replayed and will be available for 90 days following the call, available on the investor relations page of Navidea's corporate website at www.navidea.com.

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. The development

activities of the Manocept immunotherapeutic platform are being conducted by Navidea in conjunction with its subsidiary, Macrophage Therapeutics, Inc. Navidea's strategy is to deliver superior growth and stockholder 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: any future actions by Platinum-Montaur; general economic and business conditions, both nationally and in our markets; our history of 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; our expectations and estimates concerning future financial performance, financing plans and the impact of competition; our ability to raise capital sufficient to fund our development and commercialization programs; our ability to implement our growth strategy; anticipated trends in our business; advances in technologies; our ability to comply with the NYSE American continued listing standards; our ability to maintain effective internal control over financial reporting; 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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Source: Navidea Biopharmaceuticals, Inc.