October 9, 2020

Navidea Biopharmaceuticals Announces Acceptance of Abstract for Presentation at the American College of Rheumatology Annual Meeting

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 American College of Rheumatology ("ACR") has accepted the results from the Company's second interim analysis of its ongoing NAV3-31 Phase 2b clinical study for presentation at the ACR Annual Meeting ("ACR Convergence 2020") under the title, "Tc99m Tilmanocept Imaging Is an Early Predictor of Clinical Response in Rheumatoid Arthritis Patients Beginning New Anti-TNFα Therapy."

This year's annual meeting will be conducted as a virtual conference from November 5-9, 2020. Navidea's abstract is accessible online at acrabstracts.org, abstract number 1544, with presentation of the poster on Monday, November 9, 2020 from 9:00 am – 11:00 am Eastern. The poster abstract will also be published in an online supplement of the journal *Arthritis & Rheumatology*.

Navidea's NAV3-31 Phase 2b trial titled "Evaluation of the Precision and Sensitivity of Tilmanocept Uptake Value (TUV) on Tc99m Tilmanocept Planar Imaging" has three arms: Arm 1 consists of healthy subjects, Arm 2 is comprised of patients with active, moderate-to-severe rheumatoid arthritis ("RA") who are on stable therapy, and Arm 3 is a pilot arm of the upcoming Phase 3 trial assessing the ability of Tc99m tilmanocept to provide an early indicator of efficacy of anti-tumor necrosis factor ("TNF") alpha treatment in RA patients.

This second interim analysis was designed to examine data from Arm 3 of the study in order to evaluate the magnitude of change of Tc99m tilmanocept signal localized to RA-involved joints in patients before and after treatment with an anti-TNF alpha therapy as well as to examine whether this change in localization, if any, can serve as an early, quantifiable predictor of treatment efficacy.

A total of 15 subjects with active moderate-to-severe RA were included in this interim analysis, each of whom were set to begin a new or first-time treatment regimen with an anti-TNF alpha therapy. Whole body and hand/wrist planar gamma camera images were obtained at baseline prior to initiation of new treatment, again at 5 weeks post therapy initiation, and then again at 12 weeks on 11 of the 15 subjects at the time of this analysis. A panel of established clinical assessments was performed at each time point as well, in order to compare imaging results with clinical standards over the 12-week time course. Results of the preliminary analysis demonstrated:

- Tc99m tilmanocept imaging from baseline to week 5 was predictive of clinical outcome at 12 weeks in 9 out of 11 subjects with 12-week clinical assessment available at the time of the interim analysis.
- Combined data from all 15 subjects in Arm 3 suggest a wide dynamic range of more than one order of magnitude (>10-fold) for calculated global Tc99m tilmanocept uptake values in joints with RA-involved inflammation.
- The wide dynamic range of global Tc99m tilmanocept signal readout combined with the low variability of imaging signal quantification established in Arms 1 and 2 of this trial are supportive of the idea that clinically meaningful changes in signal localization can be detected.
- These preliminary results indicate that marked changes in Tc99m tilmanocept global uptake values by week 5 presage clinical efficacy evaluations at week 12 of treatment.

These data are supportive of Navidea's hypotheses that Tc99m tilmanocept imaging can provide quantifiable imaging assessment of RA-involved joints that enables early prediction of clinical response as well as longitudinal monitoring of clinical status.

Dr. Michael Rosol, Chief Medical Officer for Navidea, said, "We are delighted by the recognition of the importance of our Phase 2b interim results by the ACR Convergence 2020 scientific committee and the opportunity to present our results at this internationally recognized meeting." Dr. Rosol continued, "This is the type of external validation of our work that reflects the great medical need for a robust, objective, noninvasive means of assessing inflammation in RA-involved joints. It is our expectation that Tc99m tilmanocept can address this need and provide critical information for rheumatologists to put their patients on the correct therapeutic pathway earlier than is currently possible."

Jed Latkin, Navidea's Chief Executive Officer, said, "It's a great honor that our clinical trial results in RA have been regularly accepted for presentation at international meetings the last several years, and this acceptance by ACR continues that record of success."

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.

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.

References and links to websites have been provided as a convenience, and the information contained on such websites is not incorporated by reference into this press release. Navidea is not responsible for the contents of third-party websites.

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