June 3, 2020

Navidea Biopharmaceuticals Announces Acceptance of Abstract for Presentation at the European League Against Rheumatism (EULAR) Congress

DUBLIN, Ohio, June 03, 2020 (GLOBE NEWSWIRE) -- via NEWMEDIAWIRE -- Navidea Biopharmaceuticals, Inc. (NYSE American: NAVB) ("Navidea" or the "Company"), a company focused on the development of precision immunodiagnostic agents and immunotherapeutics, is pleased to announce that the results from the Company's first interim analysis of its ongoing NAV3-31 phase 2b clinical study will be presented as a poster at the European League Against Rheumatism ("EULAR") Congress 2020. The poster is titled, "A Phase 2b Study of Intravenously Administered Tc 99m Tilmanocept to Determine Differential Uptake, Reproducibility Over Time and Image Stability in Healthy Subjects and in Patients with Rheumatoid Arthritis ("RA") on Stable Treatment."

The aim of this interim analysis of the phase 2b study was to evaluate reproducibility and stability of imaging and to assess quantitative Tc99m tilmanocept uptake cut points that can reliably enable discrimination between joints of healthy people and RA patients. Results were supportive of the hypothesis that Tc99m tilmanocept imaging can provide robust, quantifiable imaging in healthy control ("HC") and RA subjects. No disease-related localization in the hands and wrists were observed in HC subjects. Localization in RA subjects was observed at levels consistent with macrophage densities observed in other studies evaluating RA synovial biopsies. Active RA images exhibit the same localization patterns on test-retest images taken on the same day as well as in subjects with images acquired on one day and again 8 days later. Results show low imaging readout variability with root mean squared differences that are approximately 10% or less of the observed localization of Tc99m tilmanocept, enabling reliable quantification of joints with RA-involved macrophage-mediated inflammation. Analysis of the HC and RA images was used to determine initial quantitative "cut-points" to differentiate between joints with and without the inflammation typically seen in RA.

The EULAR Scientific Committee informed all participants that this year's face-to-face annual congress slated to be held in Frankfurt, Germany, June 3-6, 2020 will now be conducted as a virtual congress experience. The eCongress will be available online under the abstract number THU0540 on the EULAR 2020 website. The poster abstract will also be published in the "*Annals of Rheumatic Diseases*."

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 EULAR congress committee and the opportunity to present our results at this international 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. With these results, along with our more recent interim look results announced on May 21, 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 EULAR continues that record of success."

Note that this news was under embargo by EULAR until 12:01 am CET June 3, 2020.

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 our current studies and potential results, FDA approval process, ability to provide rheumatologists and those suffering from RA with expected benefits, the accuracy and timing of our imaging as an indication of treatment effectiveness, the use of our imaging as part of treatment for RA patients, our ability to progress into a Phase 3 study, our ability to successfully develop products, and the role of Navidea in the management of RA worldwide. 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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Source: Navidea Biopharmaceuticals, Inc.