October 11, 2018

Navidea Biopharmaceuticals to Present Data on the Manocept Platform at 2018 ACR 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, announced today the company will present a poster detailing results from the Company’s clinical trials assessing Tc 99m tilmanocept in rheumatoid arthritis (RA) at the American College of Rheumatology (ACR) 2018 Annual Meeting, being held October 19-24, 2018 in Chicago, Illinois. Tc 99m tilmanocept is the first product developed and commercialized by the Company based on the Manocept platform.

The Phase 1 and Phase 2 clinical trials enrolled subjects with active, moderate-to-severe RA and healthy controls (HC). Images were acquired at various time points post-injection of Tc 99m tilmanocept. Results from the completed clinical trials show that Tc 99m tilmanocept is well-tolerated with no drug-related adverse events observed. Additionally, static planar images of joints in active RA subjects demonstrated significant Tc 99m tilmanocept localization to disease-involved joints of the shoulders, knees, hands, and feet. Whole body and joint-specific static planar imaging in healthy control subjects, as expected, did not reveal joint-specific localization.

Bonnie Abbruzzese, Senior Director of Clinical Research for Navidea, said, “The ability to detect synovial macrophage activity from planar and SPECT/CT imaging makes Tc 99m tilmanocept an immunodiagnostic agent for the evaluation of joint-specific inflammation, characterization of joint-level pathobiology, and individualization of treatment.” Ms. Abbruzzese continued, “The results from the completed trials support the need for further studies to examine the correlation of tilmanocept uptake with CD206-positive synovial macrophages over time, which may provide valuable, clinically significant insight into the ability to quantitatively monitor treatment response.”

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 worldwide RA patients.

Details of Navidea’s poster presentation:

Title: “Technetium Tc 99m Tilmanocept: A Targeted Immunodiagnostic Radiopharmaceutical for the Assessment of Synovial Macrophage Activity in Rheumatoid Arthritis" (abstract #2211)
Session Title: Imaging of Rheumatic Diseases Poster III: Other Modalities
Date: Tuesday, October 23, 2018

Time: 9:00-11:00am CT

Additional information and full abstracts can be found at www.rheumatology.org

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 Tc 99m 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 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.

Reference

1. https://www.rheumatoidarthritis.org/ra/facts-and-statistics/

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. Such forward-looking statements include those relating to the Company's participation in CAP, its growth and exposure to industry participants, its marketing strategy, its potential for commercial success, and ability to establish contacts with potential collaborators, partners, and investors. 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: general economic and business conditions, both nationally and in our markets; our history of losses and uncertainty of future profitability; the final outcome of the CRG litigation in Texas; 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; and other risk factors and 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.

View source version on businesswire.com:
https://www.businesswire.com/news/home/20181011005198/en/

Navidea Biopharmaceuticals, Inc.
Jed Latkin, CEO, 614-551-3416
jlatkin@navidea.com
or
Edison Advisors
Joseph Green, 646-653-7030
jgreen@edisongroup.com

Source: Navidea Biopharmaceuticals, Inc.