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Navidea Biopharmaceuticals Announces Comparative Study to Evaluate the Potential Utility of Tilmanocept In Patients with Tuberculosis (“TB”)

- New comparative study of 68Ga-Tilmanocept and 18F-FDG PET/CT in the evaluation of patients with TB
- Purpose to evaluate the use of 68Ga-Tilmanocept as a probe to locate macrophage mannose receptor (“MR,” CD206) within TB granulomas

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 Professor Mike Sathekge, MBChB, M. Med (Nuclear Medicine), PhD Professor and Head of the Department of Nuclear Medicine in the Faculty of Health Sciences at the University of Pretoria/Steve Biko Academic Hospital, plans to initiate a comparative study evaluating the use of Tilmanocept in patients with TB.

Relevance of the Study

The purpose of the study is to explore using 68Ga-Tilmanocept as an aid in TB patient management while contributing to the better understanding of the biology of TB granulomas. The TB granuloma plays multiple roles in tuberculous infection, although much remains unknown about its biology. Macrophages constitute one of the most abundant cell types in the TB granuloma. A molecular probe such as 68Ga-labeled Tilmanocept targeting MR (CD206) expressed on macrophages, therefore, holds great promise not only in understanding the behavior of TB granulomas, but may serve as a vehicle for delivering therapeutic interventions in the future. Comparing findings on 68Ga Tilmanocept PET/CT and FDG PET/CT will contribute to the understanding of the biology of tuberculous granuloma. Navidea would provide tilmanocept for use in this study. Successful completion of this study could lead to an extended claim of 68Ga-Tilmanocept.

Principal Investigator

Professor Mike Sathekge, Principal Investigator of this study, said, “Our collaboration with Navidea promises to make pivotal contributions to the biology of the tuberculous granuloma and the development of novel targeted therapeutic interventions.”

Dr. Michael Rosol, Chief Medical Officer of Navidea, said, “We are excited to begin this comparative study in collaboration with the Department of Nuclear Medicine at the University of Pretoria. We look forward to providing updates on this study in the near future.”

“As the worldwide community further embraces TB treatments and screening to prevent the spread of the disease, we are very pleased to begin this comparative study,” said Jed Latkin, Chief Executive Officer of Navidea. “This is an exciting milestone of innovation and continued progress for Navidea.”

Latest Statistics on the TB Epidemic

TB is the most infectious killer worldwide and is also the leading cause of death among people diagnosed with HIV. In terms of TB care and prevention, TB treatments saved fifty-four million lives worldwide from 2000-2017.¹

Worldwide, TB is one of the top 10 causes of death and the leading cause from a single infectious agent (above HIV/AIDS). Millions of people continue to fall sick with TB each year. In 2017, TB caused an estimated 1.3 million deaths (range, 1.2–1.4 million) among HIV-negative people and there were an additional 300 000 deaths from TB (range, 266 000–335 000) among HIV-positive people. Globally, the best estimate is that 10.0 million people (range, 9.0–11.1 million) developed TB disease in 2017: 5.8 million men, 3.2 million women and 1.0 million children. There were cases in all countries and age groups, but overall 90% were adults (aged ≥15 years), 9% were people living with HIV (72% in Africa) and two thirds were in eight countries: India (27%), China (9%), Indonesia (8%), the Philippines (6%), Pakistan (5%), Nigeria (4%), Bangladesh (4%) and South Africa (3%). These and 22 other countries in WHO’s list of 30 high TB burden countries accounted for 87% of the world’s cases. Only 6% of global cases were in the WHO European Region (3%) and WHO Region of the Americas (3%). The severity of national epidemics varies widely among countries. In 2017, there were fewer than 10 new cases per 100 000 population in most high-income countries, 150–400 in most of the 30 high TB burden countries, and above 500 in a few countries including Mozambique, the Philippines and South Africa. Drug-resistant TB continues to be a public health crisis. The best estimate is that, worldwide in 2017, 558 000 people (range, 483 000–639 000) developed TB that was resistant to rifampicin (RR-TB), the most effective firstline drug, and of these, 82% had multidrug-resistant TB (MDR-TB). Three countries accounted for almost half of the world’s cases of MDR/RR-TB: India (24%), China (13%) and the Russian Federation (10%).²

References

- 1). https://www.who.int/tb/publications/factsheet_global.pdf?ua=
- 2). https://www.who.int/tb/publications/global_report/tb18_ExecSum_web_4Oct18.pdf?ua=1

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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Navidea Biopharmaceuticals, Inc.
Jed Latkin, CEO, 614-973-7490
jlatkin@navidea.com

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