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Navidea Biopharmaceuticals Announces the Notice of Allowance for U.S. Patent Application for Diagnosis and Treatment of Leishmaniasis

Decision of Grant given in Japan for separate patent application covering targeted delivery of payloads attached to the Manocept platform

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 has received a Notice of Allowance for the patent application titled, "Compounds And Compositions For Treating Leishmaniasis And Methods Of Diagnosis And Treating Using Same" (U.S. Patent Application No. 15/729,633). Navidea also announced that it has received a Decision of Grant from the Japan Patent Office for the patent application titled, "Compounds And Compositions For Targeting Macrophages And Other Mannose-Binding C-Type Lectin Receptor High Expressing Cells And Methods Of Treating And Diagnosing Using Same" (Japanese Patent Application No. 2020-107176).

The U.S. patent application involving leishmaniasis protects the use of Navidea's mannosylated dextran-based drug-delivery vehicles to deliver small molecule therapeutic payloads as possible therapies for leishmaniasis. Leishmaniasis is a vector-borne chronic disease caused by a protozoan parasite that replicates in CD206⁺ macrophages. It is transmitted to humans through the bite of infected phlebotomine sandflies found in parts of the tropics, subtropics, and southern Europe. Leishmaniasis is rare in the U.S., but in more tropical countries where the sandfly vectors are found, leishmaniasis is a common, serious, and potentially life-threatening disease. The World Health Organization estimates that there are 700,000-1,000,000 new cases of leishmaniasis each year. Because of this situation, leishmaniasis is classified as a neglected tropical disease, and is on the FDA's list of tropical diseases eligible to receive a priority review voucher. If further research supports the efficacy of Navidea's therapeutic constructs for treating leishmaniasis, the awarding of a priority review voucher could have significant economic value for Navidea. The Notice of Allowance concludes the substantive examination of the patent application and is expected to result in the issuance of a U.S. patent after administrative processes are completed.

The Japanese patent application titled "Compounds And Compositions For Targeting Macrophages And Other Mannose-Binding C-Type Lectin Receptor High Expressing Cells And Methods Of Treating And Diagnosing Using Same" is an important application for Navidea that claims targeted delivery of a wide range of therapeutic payloads attached to Manocept platform-based constructs using a degradable hydrazone linker. The Japanese patent application has similar claims to a corresponding patent that was previously granted

in the U.S. Ongoing work by Navidea has shown that the claimed Manocept-hydrazone constructs have potential applications for treating such diseases as cancer as well as leishmaniasis. The Japanese Patent Office Decision of Grant for this patent application strengthens Navidea's patent protection for the therapeutic constructs it is developing.

Dr. Michael Rosol, Chief Medical Officer for Navidea, said, "These patents will be key to advancing and protecting our intellectual property and to the continued development of our clinical pipeline. Our targeted therapeutics have the potential to address the large unmet medical need caused by leishmaniasis as well as other diseases of significance globally."

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.

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