

November 7, 2022



# Navidea Biopharmaceuticals Announces Details of Presentation at Upcoming Society for Immunotherapy of Cancer 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 details of the results from the Company's ongoing preclinical studies evaluating targeted immunotherapy for cancer based on the Manocept platform. The results will be presented at the 37<sup>th</sup> Annual Meeting of the Society for Immunotherapy of Cancer ("SITC") to be held at the Boston Convention & Exhibition Center in person and virtually November 8-12, 2022 in Boston, MA. These details were embargoed by SITC until the week of the meeting.

The abstract, "Synthetic CD206 Targeted Constructs Carrying Paclitaxel or Novel Bisphosphonate Payloads Alter Macrophages Towards Pro-inflammatory Phenotypes; The Paclitaxel Construct Improves the Efficacy of anti-CTLA4 in CT26 Tumors" (Abstract #1161), will be presented as a poster on November 10, 9 am to 9 pm in the conference center's poster hall.

In this study, results demonstrate that Navidea's macrophage-targeting Manocept platform technology, consisting of mannosylated amine dextrans ("MAD") and carrying the therapeutic payloads paclitaxel or a novel bisphosphonate, could drive the phenotype of macrophages *in vitro* towards a proinflammatory type (more CD80 and CD86 expression, less CD206 and CD163 expression). This is important because in tumors there exist tumor-associated macrophages ("TAMs") that are typically of the wound healing, anti-inflammatory type, and these play a key role in paradoxically shielding the tumors from the body's immune response. Driving the TAM phenotype more towards a proinflammatory state should enable both an immune response against the tumors as well as increase the efficacy of other therapies that can work alongside the body's immune system against the tumors.

In addition to the *in vitro* work using both the paclitaxel and bisphosphonate carrying constructs, *in vivo* studies using the MAD-paclitaxel construct in a mouse tumor model demonstrated that this construct increased the efficacy of an approved checkpoint inhibitor therapy, anti-CTLA4, reducing tumor growth by 76% compared to a saline control. Delivery of paclitaxel and bisphosphonates by this method also reduces off-target exposure and should limit toxicity.

Future studies will examine the effect of the MAD-bisphosphonate therapy with and without anti-CTLA4 therapy in the mouse tumor model. Preclinical toxicity studies will also be conducted en route to an Investigational New Drug ("IND") application.

Abstract title and session information can be found on the SITC Annual Meeting website at: <https://www.sitcancer.org/2022/home>.

Dr. Michael Rosol, Chief Medical Officer for Navidea, said, “We are delighted by the opportunity to present these important preclinical results at this internationally recognized meeting. These results provide support for the hypothesis that our macrophage-targeted constructs can increase the efficacy of already approved therapies to significant effect, helping to rally the body’s immune response against tumors.” Dr. Rosol continued, “We continue to develop the Manocept platform, using its potent ability to target macrophages, for the development of new immunotherapies for diseases including cancer.”

## **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](http://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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