April 20, 2022

Navidea Biopharmaceuticals Announces Updated Third-Party Asset Valuation of Tc99m Tilmanocept for Indications in Rheumatoid Arthritis for U.S. and EU Markets

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 the results of an updated third-party asset valuation of its Rheumatoid Arthritis ("RA") diagnostic product candidate for both the U.S. and EU markets.

The Company engaged the independent third-party valuation firm, LifeSci Consulting (LifeSci Partners), to perform a U.S.-focused primary market research valuation and a secondary market analysis for the EU of its advanced pipeline product Tc99m tilmanocept for prediction of treatment efficacy of anti-tumor necrosis factor alpha ("TNFα") therapy in RA. A summary of the valuation report and the assumptions on which it is based is available on the Company's website, www.navidea.com. The U.S. market evaluation has been updated from the December 2021 press release using primary information from academic and high-volume health care provider rheumatologists obtained through questionnaires and interviews (primary research).

The Company is advancing its program evaluating Tc99m tilmanocept imaging, a radiopharmaceutical that selectively targets the CD206 receptor expressed on activated macrophages, for indications in RA. A previously completed Phase 2B study demonstrated results in support of the hypotheses that Tc99m tilmanocept imaging can provide robust, quantitative imaging in healthy controls and in patients with active RA, and that this imaging can provide an early indicator of treatment efficacy in patients with active RA. The Company's active Phase 3 trial will evaluate the ability of Tc99m tilmanocept imaging to serve as an early predictor of treatment response in RA patients switching to an anti-TNFα therapy.

The valuation report used cited research and assumptions believed to conform to industry best practices. Under base-case assumptions that are discussed in the report, peak combined U.S. and EU sales could reach $1.2 billion annually, and in the upside scenario peak annual U.S. and EU sales could reach $2.6 billion. Rheumatologist feedback included recognition of the need for a tool that would enable treatment response prediction. Opportunities for added value include possible indication expansion to other classes of RA therapeutics, registration of Tc99m tilmanocept imaging as a biomarker of activated macrophages in the joints of patients with RA, and expansion into additional geographic

areas.

Dr. Michael Rosol, Navidea's Chief Medical Officer, said, "This report provides an updated third-party assessment of the potential commercial value of Tc99m tilmanocept in both the U.S. and EU markets. As with our earlier release, we present this in the spirit of transparency, while also giving investors a view into the company's internal rigor in evaluating investments in the product pipeline." Dr. Rosol continued, "We believe we are on the right path to bringing a valuable tool to bear to meet a large unmet medical need in patients with RA. Success would mean that we can provide rheumatologists and those suffering with RA a noninvasive, quantifiable, early indicator of whether or not an anti-TNFα treatment is working. This could bring enormous benefit to these patients by assisting physicians in putting them on the right course of treatment much earlier than is possible today."

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 fact that the valuation by LifeSci Partners of our Tc99m tilmanocept pipeline product is subject to and based on numerous assumptions about the commercial success of the product, expected associated costs, and the outcome of various risks, including the outcome of clinical trials, that could affect the timetable for revenues, among other assumptions, that actual outcomes are likely to vary from such assumptions, resulting in variations from the possible results set forth in the valuation report; 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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Source: Navidea Biopharmaceuticals, Inc.