

March 31, 2020



# **Navidea Biopharmaceuticals Signs Letter of Intent with WorldCare Clinical to Partner on Navidea’s Rheumatoid Arthritis Clinical Imaging Workflow and Commercialization; Other Business Updates**

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 signed a letter of intent (“LOI”) to partner with WorldCare Clinical, LLC for the Company’s rheumatoid arthritis (“RA”) diagnostic clinical imaging workflow. Per the agreement, WorldCare would serve as Navidea’s central imaging service provider following FDA approval of Navidea’s RA diagnostic. WorldCare Clinical is the world’s leading independent contract research organization dedicated to imaging in clinical trials and brings with it over 25 years of clinical trial imaging, commercial clinical imaging, and large-scale data management experience.

WorldCare and Navidea will work in conjunction during the completion of Navidea’s ongoing and planned RA diagnostic trials. The partnership will work to develop the commercial workflow and infrastructure to support the full-scale commercialization plan for Navidea’s RA diagnostic. It is anticipated that WorldCare will be the vendor managing the imaging aspects of the upcoming Phase 2b (NAV3-32) and Phase 3 (NAV3-33) clinical trials, and will work in parallel to develop an optimized workflow in preparation for commercial launch in indications in RA.

Jed Latkin, Chief Executive Officer of Navidea, said, “We are extremely pleased to partner with a world-class imaging vendor in this necessary component of our RA diagnostic workflow. As we near the Phase 3 clinical trial, we continue discussions with commercial partners, and will provide an update on developments on that front in the near future.”

Dr. Michael Rosol, Chief Medical Officer of Navidea, said, “We are excited to have this agreement in place and to select WorldCare Clinical as our imaging partner for the upcoming trials in RA. WorldCare will provide the central imaging reads that will be integral to the clinical and commercial success of Tc 99m tilmanocept in RA monitoring applications. The reach and experience that they bring to the table in managing imaging workflows in clinical trials and in the clinic has convinced us that they are the right partner for Navidea at this pivotal stage in development.”

Aaron Timm, Chief Executive Officer of WorldCare Clinical, said, “We are excited to partner with the Navidea team on their upcoming RA trials as well in the use of Tc 99m tilmanocept in RA monitoring applications. We believe that our radiological, scientific, and operational

expertise will contribute to Navidea's goal of enhancing patient care by enabling better diagnostic accuracy, clinical decision-making, and targeted treatment."

### **Receipt of Audit Opinion with Going Concern Qualification Update**

As previously disclosed in its Annual Report on Form 10-K for the fiscal year ended December 31, 2019, which was filed with the Securities and Exchange Commission on March 18, 2020, the Company's audited financial statements contained a going concern explanatory paragraph in the audit opinion from its independent registered public accounting firm. This announcement is required pursuant to NYSE American Company Guide Sections 401(h) and 610(b), and does not represent any change or amendment to the Company's financial statements or to its Annual Report on Form 10-K for the fiscal year ended December 31, 2019.

### **About WorldCare Clinical**

WorldCare Clinical is a global imaging CRO that employs scientific expertise, innovative technology, and operational excellence to maximize the precision and accuracy of a blinded independent central review of Phase I – IV clinical trial data. The company has worked with thousands of sites in more than 60 countries. WCC's robust technology platform processes over 250 million images annually (CT, MRI, X-Ray, Echo, US, PET). Originally founded in 1992 by the Massachusetts General Hospital (MGH) Department of Radiology, WorldCare continues to maintain a strategic relationship with the Harvard Hospital System as well as other leading academic institutions. For more information, please visit [www.wcclinical.com](http://www.wcclinical.com).

### **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 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, our history of operating

losses and uncertainty of future profitability, accumulated deficit, future capital needs, the outcome of any pending litigation, uncertainty of capital funding, dependence on royalties and grant revenue, limited product line and distribution channels, competition, risks of development of new products, our ability to maintain effective control over financial reporting, our ability to comply with NYSE American continued listing standards, the impact of the recent 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 [www.sec.gov](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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