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Navidea Biopharmaceuticals Appoints Michel Mikhail, Ph.D. as Chief Regulatory Officer

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 appointment of Michel Mikhail, Ph.D. as Chief Regulatory Officer of Navidea, effective October 1, 2021.

Dr. Mikhail has more than 30 years of experience in the pharmaceutical industry and a track record of achievement in R&D and international regulatory affairs at large multinational research-based pharmaceutical companies. Prior to joining Navidea, Dr. Mikhail worked in global regulatory consulting for various pharmaceutical and biotech companies from January 2016 through September 2021. Before acting as a consultant, Dr. Mikhail served in senior regulatory executive roles at BioNTech AG, Fresenius Kabi, Ranbaxy Europe Ltd. (now SunPharma), Pharmacia & Upjohn (now Pfizer), Knoll AG (now Abbvie), SmithKline Beecham (now GlaxoSmithKline), and Boehringer Ingelheim. Dr. Mikhail is a global expert in Regulatory Affairs dealing with the U.S. Food and Drug Administration ("US-FDA"), the European Medicines Agency ("EU-EMA") as well as national agencies in Europe, Japan's Pharmaceuticals and Medical Devices Agency, China's National Medical Products Administration, among other regulatory agencies worldwide. He is a Chartered Expert in Pharmacology-Toxicology. Dr Mikhail served on the Safety working group and Efficacy working group of the European Federation of Pharmaceutical Industry Associations and as a Topic Leader for new guidelines. He served on the Regulatory Group of the European branch of the Pharmaceutical Research and Manufacturers of America, on the European Biosimilars Group, the Regulatory and Scientific Affairs Group of the European Generic medicines Association (now Medicines for Europe), as well as on different associations and organizations. Dr. Mikhail is a lifetime member of The Organization for Professionals in Regulatory Affairs, and has contributed as volunteer at the Drug Information Association and the Parenteral Drug Association. Dr. Mikhail was part of the Transatlantic Trade and Investment Partnership negotiations aiming at harmonization of regulatory requirements and relying on each other's inspections between the EU-EMA and US-FDA. Dr. Mikhail served as a volunteer member of the Expert Committee of the Governmental Federal Institute of Risk Assessment in Berlin, Germany and served as a volunteer member of the Expert Committee for Toxicology of the United States Pharmacopoeia in Maryland, USA. Dr. Mikhail holds a Ph.D. from the University of Paris and a Ph.D. from the University of Hannover.

Dr. Mikhail said, "This is an exciting opportunity to join Navidea's leadership team, to expand the product portfolio leveraging on the diagnostic imaging and the therapeutic Manocept platform. I look forward to working with the US-FDA, the EU-EMA and regulatory agencies around the world and with the Navidea development teams and partners to deliver on Navidea's drug development initiatives, ensuring they are completed and approved on time

and to the highest quality standards that can lead to positive patient impact. I am proud to join a world-class team to support Navidea's anticipated growth, as we execute on our mission of helping patients have the right effective medicine from the start to treat their disease, minimizing exposure to unwanted side effects and saving cost for the payers."

Navidea Chief Executive Officer Jed Latkin said, "We are very pleased to welcome Dr. Michel Mikhail to our executive leadership team, as he brings over 30 years of expertise in the field of global regulatory affairs and drug development. He has experience in accompanying drug development through regulatory agency meetings and scientific advice, from start until successful completion of Phase 3 clinical trials as well as indication expansion and successful approval by regulatory authorities. We look forward to a successful development and implementation of regulatory strategy for development and expansion of our Manocept platform to enhance patient care and contribute to covering unmet medical needs for drug imaging technology and therapeutic use in rheumatoid arthritis and beyond."

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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