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Navidea Awarded NIH SBIR Grant for NAV4694 Beta-Amyloid Imaging Agent Phase 3 Clinical Program Aimed at Alzheimer's Disease

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAV), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced the award of a Small Business Innovation Research (SBIR) grant from the National Institute On Aging (NIA) of the National Institutes of Health (NIH) in connection with the Company's Phase 3 clinical program for its NAV4694 beta-amyloid imaging agent as an aid in the differential diagnosis of Alzheimer's disease. The SBIR grant has the potential to provide up to \$1.8 million in support, if fully funded, through the conclusion of the Phase 3 clinical study. Funding for the approved first stage of the grant (\$259,000) is intended to provide support for initiation activities of the Phase 3 clinical program. Funding of the second stage of the grant is contingent upon meeting specific aims related to the first stage of the grant such as institutional review board approval of the Phase 3 protocol, clinical site contracting and investigator training. Navidea announced the initiation of the Phase 3 program in June 2013.

"We are pleased that the NIH has recognized the potential value for NAV4694 which we believe can play an important role in clinical practice allowing for earlier diagnosis and therapeutic intervention in cases of dementia," said Frederick Cope, PhD, FACN, Navidea Senior Vice President and Chief Scientific Officer. "We expect this trial will further highlight several of the key features of NAV4694 such as high amyloid binding/sensitivity, low white matter uptake, strong signal-to-noise ratios and clear, unambiguous images. We believe that earlier and more effective diagnosis is directly in line with the federal government's aim to address the impact of this devastating disease. We very much appreciate the support of the NIH as we conduct this pivotal Phase 3 clinical trial."

"The pivotal Phase 3 study is designed to provide a direct comparison of NAV4694 patient images collected during life with postmortem histopathology findings. The results from this study may lead to improved differential diagnosis and patient management," said Cornelia Reininger, MD, PhD, Navidea Senior Vice President and Chief Medical Officer. "NAV4694 is a great example of a precision diagnostic agent with the potential to help physicians overcome the frequent challenges of diagnostic uncertainty and provide millions of patients with more accurate diagnoses."

About NAV4694

NAV4694 is a Fluorine-18 labeled precision radiopharmaceutical candidate intended for use in Positron Emission Tomography (PET) imaging and evaluation of patients with signs or

symptoms of cognitive impairment such as Alzheimer's disease (AD). NAV4694 binds to beta-amyloid deposits in the brain that can then be imaged in scans. Beta-amyloid plaque pathology is widely used in the diagnosis of AD. The ability of NAV4694 imaging to display amyloid plaque pathology may enable earlier identification of AD and improve monitoring of disease progression and interpretation of brain scan images. Navidea has an ongoing NAV4694 Phase 2b trial in Mild Cognitive Impairment and a Phase 3 program for NAV4694 in AD.

About Alzheimer's

Alzheimer's disease (AD) is a progressive and fatal neurodegenerative disease which affects a person's memory and ability to learn, reason, communicate and carry out daily activities. Increasing age is the greatest risk factor for AD and there is no prevention or cure. The World Health Organization estimates that Alzheimer's disease affects over 24 million people worldwide. Currently in the U.S. alone, there are over 5 million Alzheimer's patients with estimates that by 2050, as many as 14 million Americans could have the disease according to the Alzheimer's Association. Among the brain changes believed to contribute to the development of Alzheimer's are the accumulation of the protein beta-amyloid *outside* nerve cells (neurons) in the brain and the accumulation of the protein tau *inside* neurons. Approximately 75 to 100 experimental technologies aimed at diagnosing, slowing or stopping the progression of Alzheimer's are now in human clinical trials.

About Navidea Biopharmaceuticals Inc.

Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAVB) is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. Navidea is actively developing four radiopharmaceutical agent platforms – Lymphoseek® (technetium 99m tilmanocept) Injection, NAV4694, NAV5001 and RIGScan™ – to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and, ultimately, patient care. Navidea's first commercial agent, Lymphoseek, was approved by the FDA in March 2013. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel radiopharmaceutical agents and advancing the Company's pipeline through selective acquisitions, global partnering and commercialization efforts. For more information, please visit www.navidea.com.

The Private Securities Litigation Reform Act of 1995 (the Act) provides a safe harbor for forward-looking statements made by or on behalf of the Company. Statements in this news release, which relate to other than strictly historical facts, such as statements about the Company's plans and strategies, expectations for future financial performance, new and existing products and technologies, anticipated clinical and regulatory pathways, and markets for the Company's products are forward-looking statements within the meaning of the Act. The words "believe," "expect," "anticipate," "estimate," "project," and similar expressions identify forward-looking statements that speak only as of the date hereof. Investors are cautioned that such statements involve risks and uncertainties that could cause actual results to differ materially from historical or anticipated results due to many factors including, but not limited to, the Company's continuing operating losses, uncertainty of market acceptance of its products, reliance on third party manufacturers, accumulated deficit, future capital needs, uncertainty of capital funding, dependence on limited product

line and distribution channels, competition, limited marketing and manufacturing experience, risks of development of new products, regulatory risks and other risks detailed in the Company's most recent Annual Report on Form 10-K and other Securities and Exchange Commission filings. The Company undertakes no obligation to publicly update or revise any forward-looking statements.

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