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Navidea Biopharmaceuticals Announces Positive Initial Results in Single-Center Cohort from Phase 2b Trial of NAV4694 in Subjects with Mild Cognitive Impairment (MCI)

- NAV4694 generates highly differentiated PET images in assessment of progression of MCI to Alzheimer's Disease -

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that the Company's investigational beta-amyloid imaging agent, NAV4694, produced highly differentiated images in the first cohort of subjects enrolled in the Company's Phase 2b positron emission tomography (PET) imaging study of subjects with Mild Cognitive Impairment (MCI). The subjects were enrolled and evaluated at the Alzheimer's Disease Center at Quincy Medical Center, Quincy, MA. The results indicate that NAV4694 produced high-quality diagnostic images that segregated MCI subjects into two discrete groups, either amyloid-positive or amyloid-negative.

The image evaluation was performed on twelve subjects meeting pre-defined inclusion/exclusion criteria for emerging, or early-stage, cognitive impairment. NAV4694 scans were assessed by two independent readers using a 3-point visual scale. Image interpretation used the Company's proprietary visual-read algorithm. All twelve MCI subjects segregated into either amyloid-positive or amyloid-negative categories. The technical quality of the scans was good and both raters were in complete agreement on the 3-point scale, with 8 scans highly positive for β-amyloid and 4 scans negative. There were no intermediate ratings or ambiguous cases despite the early-stage characterization of the subjects' cognitive impairment status. The scans were easy to read and the readers noted that the high gray matter relative to white matter signal made image interpretation very straight forward. To date, the product candidate appears to be safe and well-tolerated. Results are expected to be presented at an upcoming scientific conference on Alzheimer's disease (AD).

"We are very pleased with the diagnostic image quality of NAV4694 in patients with mild cognitive impairment, offering the potential to identify individuals who are at high risk of developing dementia caused by AD before their symptoms become severe," said Dr. Anil K. Nair, MD, Chief of Neurology and Head of the Alzheimer's Disease Center at Quincy Medical Center. "These patients are routinely the most difficult to diagnose. The images generated using NAV4694 are easy to interpret and have resulted in the segregation of early-stage patients into two discrete categories: those with positive scans versus those with negative scans. We are encouraged at the potential to separate patients with emerging disease,

enabling earlier and more accurate differentiation of MCI subjects who are at risk of developing AD from those who are not and before the disease has advanced to the stage of impairing daily activities. If AD could be diagnosed at an earlier stage, before clinical dementia has fully developed, the potential for successful intervention with current and future treatments could be improved considerably."

"We are very pleased with the performance of NAV4694 in this initial MCI cohort and with the progress of the Phase 2b trial in general," commented Cornelia Reininger, MD, PhD, Navidea's Senior Vice President and Chief Medical Officer. "Results to date across all Phase 2 studies indicate the efficacy of NAV4694 in detecting beta-amyloid while exhibiting low white-matter uptake for clearer images, which may be one reason for the promising results obtained in this initial assessment of subjects with MCI."

Dr. Reininger continued, "As the dementia field moves to earlier evaluation and treatment of cognitive impairment, it is of increasing importance to have diagnostic agents that can accurately detect the underlying cause. Our ultimate goal is to provide an improved diagnostic tool with outstanding performance characteristics for physicians to aid in the diagnosis of Alzheimer's disease and other forms of neurodegenerative dementia."

NAV4-04 is a Phase 2b, open-label, multiple-center, non-randomized, PET imaging study to assess the safety and efficacy of NAV4694 in subjects diagnosed with MCI to investigate whether NAV4694 has the ability to detect beta-amyloid in PET scans in subjects with MCI. Enrollment is ongoing and is expected to accelerate in conjunction with the expanded availability of the NAV4694 tracer following the recent completion of technical transfer activities at PET manufacturing facilities.

Information on the protocol and enrolling sites for this study (NAV4-04) can be found at: http://www.clinicaltrials.gov/ct2/show/NCT01812213?term=Navidea&rank=4.

About NAV4694
NAV4694 is an investigational 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's Phase 3 program for NAV4694 in AD is also underway.

About Mild Cognitive Impairment
Mild cognitive impairment (MCI) is a condition in which people have memory or other thinking problems greater than normal for their age and education.[1] People with mild cognitive impairment are at increased risk of progressing to dementia due to Alzheimer's disease (AD) or other causes. New therapies are on the horizon that offer the potential to modify the trajectory of AD. To be most effective, these new therapies will most likely need to be administered early in the progression of a patient's illness when their cognitive symptoms are least severe. Patients with MCI and the underlying pathology associated with AD would be candidates for treatment with these new AD therapies, while MCI patients with other pathologies would not. Imaging studies that can visualize beta-amyloid deposits in the brains of living patients will become a key component of the diagnostic protocol that

identifies these patients which will enable the most effective use of these new therapies.

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 developing multiple precision diagnostic products and platforms including NAV4694, NAV5001, Manocept™ and RIGScan™, to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and, ultimately, patient care. Lymphoseek® (technetium 99m tilmanocept) Injection, Navidea's first commercial product from the Manocept platform, 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.

[1] National Institute on Aging: About Alzheimer's Disease: Mild Cognitive Impairment, http://www.nia.nih.gov/alzheimers/topics/mild-cognitive-impairment. Accessed August 28,

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