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Navidea Biopharmaceuticals Announces Enrollment of First Subject in Phase 2b Trial of NAV4694 in Subjects with Mild Cognitive Impairment (MCI)

- Study to evaluate NAV4694 in monitoring 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 enrollment has commenced in its Phase 2b, open-label, safety and efficacy positron emission tomography (PET) imaging study of [^{18}F]NAV4694 for detection of cerebral β-amyloid plaque in subjects diagnosed with Mild Cognitive Impairment (MCI). The study is designed to investigate whether NAV4694 positron emission tomography (PET) scan findings have the ability to distinguish subjects with MCI who progress to Alzheimer's disease (AD) from those who do not. Enrollment is currently planned at approximately five sites throughout the U.S. The first patient has been enrolled by the Alzheimer's Disease Center at Quincy Medical Center in Quincy, MA.

"We are pleased to participate in this important clinical study of NAV4694 aimed at evaluating a patient population in whom dementia is just emerging and for whom it is believed the best prospects for therapeutic intervention will exist," said Dr. Anil K. Nair, MD, Chief of Neurology and Head of the Alzheimer's Disease Center at Quincy Medical Center in Quincy, MA. "Clinical trial results to date indicate that NAV4694 shows favorable sensitivity and specificity in detecting β-amyloid while exhibiting low white-matter uptake for clearer images that may assist in differential diagnoses associated with MCI. 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."

"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. To our knowledge this is the first prospective, multi-center study to evaluate a radiopharmaceutical β-amyloid agent solely in subjects with MCI, an area of extreme importance as Alzheimer's disease is expected to impact as many as 14 million Americans by 2050," commented Cornelia Reininger, MD, PhD, Navidea's Senior Vice President and Chief Medical Officer. "The outcome of this trial may enable accurate differentiation of MCI subjects who are at risk of developing Alzheimer's disease from those who are not before the disease has reached more advanced stages that can impair activities of daily living. 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 PET scan findings have the ability to distinguish subjects with MCI who progress to AD from those who do not. In conjunction with neuro-cognitive testing examinations, subjects will receive three injections of the investigational, diagnostic agent during a 36 month period: at baseline, 18 months and 36 months. Assessment of NAV4694 efficacy will be based on the sensitivity, specificity, and the negative and positive predictive value of the NAV4694 PET scan findings in predicting progression from MCI to AD over 36 months. The overall Standard of Truth assessment as to cognitive state (e.g., cognitive decline and/or progression to dementia) will be performed by an investigator who will be blinded to the results of NAV4694 PET findings.

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 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 β -amyloid deposits in the brain that can then be imaged in scans. Amyloid plaque pathology is standardly used in the diagnosis of AD so the ability of NAV4694 combined with amyloid plaque pathology may enable earlier identification of AD and improve monitoring of disease progression and interpretation of brain scan images. Navidea plans for a Phase 3 trial of NAV4694 to begin in 2013.

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 24,000,000 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 β -amyloid *outside* nerve cells (neurons) in the brain and the accumulation of the protein tau *inside* neurons. Approximately 75 to 100 experimental therapies 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®, 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 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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