September 18, 2012

Navidea Biopharmaceuticals Announces Enrollment of First Subject in Phase 2 Trial of NAV4694 as an Aid in Diagnosing 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 at two sites participating in its Phase 2, open-label, safety and efficacy PET imaging study of [^{18}F]NAV4694 for detection of cerebral β-amyloid plaque in subjects diagnosed with probable Alzheimer's disease (AD). The study is designed to compare images from subjects with probable AD with similarly aged and young healthy volunteers (HV). Two trial sites are currently enrolling subjects: Molecular NeuroImaging, LLC in New Haven, CT, which dosed the first patient in the study; and the Alzheimer's Disease Center at Quincy Medical Center in Quincy, MA.

"We are pleased to participate in this clinical study of NAV4694 which has the potential to help advance diagnostic accuracy in people with Alzheimer's disease," said Danna Jennings, M.D., Clinical Research Director, Molecular NeuroImaging, LLC. "NAV4694 appears to exhibit the strengths of ^{11}C PIB but given that the ligand is labeled with 18 F it offers flexibility and is more practical to use. The data at this point in the development suggest that NAV4694 shows favorable sensitivity, specificity and decreased white-matter uptake that may enable earlier Alzheimer's disease identification, better monitoring of disease progression, and easier scan interpretation."

"In addition to safety and efficacy endpoints, this clinical trial will allow us to evaluate NAV4694 to determine the correlation of the clinical diagnosis with the β-amyloid plaque uptake in PET images of subjects diagnosed with probable AD," commented Frederick Cope, Ph.D., F.A.C.N., C.N.S., Navidea's Senior Vice President, Pharmaceutical Research and Clinical Development. "Our ultimate goal is to provide an improved diagnostic tool with outstanding performance characteristics for physicians to aid in the diagnosis of AD, a disease expected to impact as many as 16 million Americans by 2050."

This is a phase 2, open-label, multiple-center, non-randomized single dose, PET imaging study to assess the safety and efficacy of [18F]NAV4694 in detecting β-amyloid plaque in the brain in subjects with probable Alzheimer's disease compared with similarly aged and young healthy volunteers. In addition to safety and efficacy objectives, this study also will measure the correlation between neuro-psychiatric test results with the amount of β-amyloid determined by the NAV4694 imaging.

Information on the protocol and enrolling sites for this study (NAV4-01) can be found at: http://www.clinicaltrials.gov/ct2/show/NCT01680588?term=NAV4&rank=1

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 early 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 16 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, CFT 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.

Investor:
Navidea Biopharmaceuticals, Inc.
Brent Larson, 614-822-2330
Sr. VP & CFO

Source: Navidea Biopharmaceuticals, Inc.