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Navidea Biopharmaceuticals Initiates Enrollment in Global Phase 3 Trial of NAV4694 PET Imaging Agent

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced the first subject has been enrolled in its NAV4694 global, pivotal Phase 3 clinical trial. The trial will assess the safety and efficacy of NAV4694, an investigational PET imaging agent, in detecting cerebral β-amyloid in end-of-life subjects with and without the diagnosis of dementia. The study will examine the effectiveness of NAV4694 in detecting the presence or absence of β-amyloid deposition in the brain by directly correlating the PET image findings during life with those of the brain tissue upon autopsy after death.

Currently, only an autopsy can confirm that a person has Alzheimer's disease. “Knowing if a patient has Alzheimer’s pathology in life would lead to improved diagnosis and patient management,” said Frederick Cope, PhD, FACN, Senior Vice President and Chief Scientific Officer at Navidea. “This study, which is designed to provide a direct comparison of patient images collected during life using a β-amyloid PET imaging agent with postmortem histopathology findings, has the potential to aid the advancement of neurodegenerative disease research and patient care.”

“We are excited to begin this pivotal Phase 3 trial for NAV4694. We believe that β-amyloid imaging has the potential to play an increasingly important role in clinical practice allowing for earlier diagnosis and therapeutic intervention,” said Connie Reininger, MD, PhD, Navidea’s Senior Vice President and Chief Medical Officer. “Results from earlier trials using NAV4694 support our conviction that the outstanding performance characteristics of this imaging biomarker, which include favorable sensitivity, specificity, rapid brain uptake and improved image clarity due to low white-matter uptake, position NAV4694 as a true ‘best-in-class’ second generation agent to aid in the diagnosis of Alzheimer’s disease and with the potential to enable diagnosis earlier in the course of disease.”

About the NAV4694 Phase 3 Clinical Trial

This study, NAV4-02, is a Phase 3, open-label, multiple-center, non-randomized study to assess the safety and efficacy of NAV4694 PET imaging in detecting cerebral β-amyloid in subjects during life when directly compared to brain histopathological evaluation at autopsy. The trial will enroll up to 275 end-of-life individuals in two cohorts either, 1) subjects diagnosed with probable Alzheimer’s disease or other form of dementia, or, 2) non-demented volunteers. The efficacy of NAV4694 PET for the detection of β-amyloid will be determined by the sensitivity and specificity of visual interpretation of NAV4694 uptake in the PET scans by blinded readers compared with the presence/absence of β-amyloid upon histopathological evaluation of the respective postmortem brain specimen in each subject.

To learn more see the study listing on ClinicalTrials.gov http://www.clinicaltrials.gov/ct2/show/NCT01886820?term=navidea&rank=3.

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. β-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 β -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®, 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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