September 4, 2013

# Navidea Awarded an Additional NIH SBIR Grant for NAV4694 Beta-Amyloid Imaging Agent for Study in Mild Cognitive Impairment

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAVB), 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 development of the Company's NAV4694 beta-amyloid imaging agent. This grant, which follows the recent SBIR award for the Company's Phase 3 study with NAV4694, will partially support the Phase 2b clinical study which is evaluating NAV4694 as a diagnostic imaging agent that may aid physicians in identifying those individuals with MCI who are at greatest risk of progressing to Alzheimer's disease (AD). The SBIR grant has the potential to provide up to $2.3 million in support, if fully funded, through the conclusion of the clinical study. Funding for the approved first stage of the grant ($152,000) is intended to provide support for initiation activities of the clinical trial 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 clinical site contracting, investigator training and institutional review board approvals. Navidea announced the initiation of the Phase 2b trial in March 2013.

"There is a great clinical need to develop better methods to identify individuals who are at high risk of developing dementia caused by AD before their symptoms become severe. Beta-amyloid plaque, which is indicative of AD, begins to appear in the brains of AD patients many years before they develop dementia," said Cornelia Reininger, MD, PhD, Navidea Senior Vice President and Chief Medical Officer. "The outcome of this trial may enable earlier and accurate differentiation of MCI subjects who are at risk of developing AD from those who are not, before the disease has advanced to the stage of impairing daily activities. If diagnosed at an earlier stage, the avenues for disorder management and therapeutic intervention could be improved considerably."

"We very much appreciate the additional support of the NIH as we conduct this valuable clinical trial aimed at evaluating a patient population in whom dementia is just emerging," said Frederick Cope, PhD, FACN, Navidea Senior Vice President and Chief Scientific Officer. "Earlier and more effective diagnosis of cognitive impairment and dementia is clearly a priority of the federal government's initiative to address important medical unmet needs in these areas. We believe the strong biochemical performance elements embodied in NAV4694 such as high amyloid binding and low white matter uptake for clearer images may differentiate NAV4694 in the effort to assist in earlier differential diagnoses in patients with disorders such as MCI."

NAV4-04 is a Phase 2b, open-label, multi-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 are planned to receive three injections of the investigational, diagnostic agent during a 36 month period: at baseline, 18 months and 36 months. The study will determine the specificity of NAV4694 PET imaging to identify the portion of all MCI patients that are at high risk of developing AD dementia and will estimate the rate of progression of the MCI patients with beta-amyloid deposits to AD dementia. 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 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 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 AD affects over 24 million people worldwide. Currently in the U.S. alone, there are over 5 million AD 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 AD 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 AD 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.*

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, 2013.

Navidea Biopharmaceuticals
Brent Larson, 614-822-2330
Executive VP & CFO
or
Stern Investor Relations, Inc.
Beth DelGiacco, 212-362-1200

Source: Navidea Biopharmaceuticals, Inc.