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# Navidea and Collaborator Molecular Neuroimaging Enroll First Subject in NAV5001 Clinical Trial

**Study to investigate [$^{123}$I] NAV5001 SPECT imaging as a tool to evaluate dopamine transporters in the brain as start of program in Dementia with Lewy Bodies**

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that collaborators at Molecular Neuroimaging, LLC (MNI) in New Haven, CT have enrolled the first subject in a clinical study to investigate the performance of [$^{123}$I]NAV5001 in a SPECT imaging procedure in connection with Navidea's program to evaluate NAV5001 in Dementia with Lewy Bodies (DLB).

"This collaborative investigator-initiated study is an important first step in recommencing a full clinical development program for NAV5001 since our in-licensing this candidate in late 2012," said Dr. Mark Pykett, Navidea's President and CEO. "Collaborations such as this are integral to Navidea's strategy to efficiently and effectively advance the development of our promising radiopharmaceutical pipeline and representative of our focus of being a leader in the field of precision diagnostics."

"The study is the first leg of our program to evaluate the utility of NAV5001 in DLB, the leading form of dementia after Alzheimer's disease and an important potential indication for NAV5001 medically and commercially," commented Cornelia Reininger, MD, PhD, Navidea's Senior Vice President and Chief Medical Officer. "During 2013, we look forward to following this study with the initiation of a Company-sponsored Phase 2b study of NAV5001 in DLB as well as the anticipated start of the Company's pivotal parallel Phase 3 registration studies of NAV5001 as an aid in the differential diagnosis of Parkinsonian syndromes."

The goal of this single center, open-label, investigator-initiated study will be to assess the distribution, safety and tolerability of NAV5001 as an agent to evaluate the integrity of the dopamine transporters in the brain, using healthy volunteers. NAV5001 is an investigational radiopharmaceutical imaging agent being developed as an aid in the differential diagnosis of Parkinsonian syndromes, including Parkinson's disease (PD) and other movement disorders, as well as Dementia with Lewy Bodies (DLB). Danna Jennings, MD, Clinical Research Director at MNI will lead the investigator-initiated clinical study.

**About NAV5001**

[$^{123}$I]NAV5001 is a patented, novel, small molecule radiopharmaceutical used with single photon emission computed tomography (SPECT) imaging to identify the status of specific regions in the brains of patients suspected of having Parkinson's disease. The agent binds to

the dopamine transporter (DAT) on the cell surface of dopaminergic neurons in the striatum and substantia nigra regions of the brain. Loss of these neurons is a widely recognized hallmark of Parkinson's disease and other forms of parkinsonism.

NAV5001 has been administered to more than 600 subjects in multi-phase clinical trials to date. Results from these clinical trials have demonstrated that NAV5001 has high affinity for DAT and rapid kinetics which enable the generation of clean diagnostic images quickly, beginning within approximately 20 minutes after injection. In addition to its potential use as an aid in the differential diagnosis of Parkinsonian's disease and movement disorders, NAV5001 may also be useful in the diagnosis of DLB, which after Alzheimer's disease, is one of the most common forms of dementia.

**About Dementia with Lewy bodies**

Most experts estimate that **Dementia with Lewy bodies (DLB)** is the second most common cause of progressive dementia after Alzheimer's disease, accounting for 15 percent of all dementia cases. The main symptoms of DLB include 1) fluctuating cognition, 2) recurrent hallucinations, and 3) parkinsonian symptoms such as rigidity and the loss of spontaneous movement.[1] The symptoms of DLB are caused by the build-up of Lewy bodies – accumulated bits of alpha-synuclein protein -- inside the nuclei of neurons in areas of the brain that control particular aspects of memory and motor control.[2] Since Lewy bodies tend to coexist with Alzheimer's brain changes and the similarity of symptoms between DLB and Parkinson's disease, doctors often find it difficult to make a definitive diagnosis. Accurate differential diagnosis of DLB is particularly important because many DLB patients have severe sensitivity to neuroleptic drugs used to treat AD.[1]

**About Navidea**

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.*

References:

[1] McKeith IG et al: Diagnosis and management of dementia with Lewy bodies. Third report of the DLB consortium. Neurology 2005; 65: 1863-1872.

[2] *NINDS Dementia With Lewy Bodies Information Page. Accessed 4/1/2013 at: http://www.ninds.nih.gov/disorders/dementiawithlewybodies/dementiawithlewybodies.htm*

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