December 3, 2013

Navidea Biopharmaceuticals Initiates Pivotal Phase 3 Registration Program of NAV5001 SPECT Imaging Agent for Parkinson's Disease

- Phase 3 Studies to Evaluate the Use of NAV5001 as an aid in the differential diagnosis of Parkinsonian Syndromes from non-Parkinsonian tremor -

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 one of the two planned NAV5001, pivotal Phase 3 clinical trials. The trial will assess the safety and efficacy of NAV5001, an investigational imaging agent as an aid in the differential diagnosis of Parkinsonian Syndromes from non-Parkinsonian tremor. NAV5001 is an investigational imaging agent used to visualize dopamine transporter protein (DAT) located on the nigrostriatal neurons in the brain using single photon emission tomography (SPECT) imaging. Loss of these neurons is a widely recognized hallmark of Parkinson's disease and other forms of Parkinsonism.

"Reducing diagnostic uncertainty and error rates for patients with movement disorders who often exhibit similar clinical symptoms would afford great value, especially early in the initial clinical presentation, and may lead to improved clinical decision-making and patient management," said Ira Goodman, MD, Principle Investigator, Compass Research, LLC, Orlando, FL. "We look forward to evaluating the attributes of NAV5001 as, unlike other agents, its rapid kinetics indicate that we can scan patients very quickly following injection. This is beneficial both for elderly patients and other patients displaying movement symptoms, as well as providing an avenue toward enhanced efficiency, productivity and patient management in the clinic."

"We are excited to begin this pivotal Phase 3 trial for NAV5001. We believe that NAV5001 has the potential to play an important role in clinical practice where physicians often struggle with the differential diagnosis of movement disorders and tremors such as are present in Parkinson's disease," said Cornelia Reininger, MD, PhD, Navidea's Senior Vice President and Chief Medical Officer. "This registration program will focus on patients with emerging symptoms in whom diagnostic uncertainty and unmet need are highest. Results from earlier trials using NAV5001 suggest that it may be an effective, well-tolerated imaging agent. The high affinity for DAT with resulting clear images can assist physicians in reaching an accurate diagnosis sooner, and the rapid kinetics with minimal time between injection and scanning and time in the SPECT scanner not only decrease patient exposure and but also facilitate increased efficiency with potential cost savings for the nuclear medicine facility."

About the NAV5001 Phase 3 Clinical Program

The open-label, pivotal NAV5001 Phase 3 program consists of two similar clinical trials that will run in parallel and enroll approximately 550 total subjects who exhibit early stage tremor. Each Phase 3 trial was the subject of a special protocol assessment (SPA) agreement with FDA. The primary endpoint of both studies is to evaluate the relative diagnostic efficacy of the NAV5001 SPECT images compared with the diagnosis made by neurologists and that established by a consensus panel of three movement disorder specialists as the 'Standard of Truth'. In one study, each subject will undergo SPECT imaging with NAV5001 only. In the second study, subjects will undergo SPECT imaging with both NAV5001 and an alternative SPECT agent, ioflupane, in a cross-over comparison design. To learn more, see this study listing on ClinicalTrials.gov: http://www.clinicaltrial.gov/ct2/show/NCT01950455?term=NAV5001&rank=1

About NAV5001
Iodine-123 labeled 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 syndromes and movement disorders, NAV5001 may also be useful in the diagnosis of Dementia with Lewy Bodies (DLB), which is the second most common cause of progressive dementia after Alzheimer's disease.

About Parkinsonian Syndromes, Parkinson's Disease and other movement disorders
Parkinsonian syndromes and movement disorders such as Essential Tremor represent a class of neurodegenerative diseases with important diagnostic needs. Parkinsonian syndromes (PS) are neurodegenerative disorders that affect a person's ability to control movement and other muscle functions. Parkinson's Disease is the most common form of Parkinsonian Syndromes believed to be caused by loss of dopamine producing neurons in the brain and with first symptoms such as tremor, rigidity, or slow movement. Other less common Parkinsonian Syndromes include multiple system atrophy (MSA), Progressive Supranuclear Palsy (PSP), and drug-induced Parkinsonism. The Parkinson's Disease Foundation (PDF) estimates that up to 10 million people worldwide are living with PD, including 1 million people in the U.S. Approximately 60,000 new cases of PD are diagnosed in the U.S. each year.[1] The International Essential Tremor Foundation estimates that as many as 10 million people in the United States are afflicted by essential tremor.

PD is commonly misdiagnosed or completely missed in clinical evaluations as symptoms are often attributed to the normal aging process. Essential tremor and the other similar conditions are also common sources of confusion in PD diagnosis. Collectively, there are over 25 million people in the U.S. and Europe with some type of movement disorder, comprising a large differential diagnosis population.

About Compass Research, LLC

Compass Research is a multi-therapeutic, phase 1-4 clinical research company headquartered in Orlando, FL, with additional research centers located in Oviedo and Leesburg, FL. With proven experience since 1992, Compass has grown in size and industry presence to become one of the premier research sites in the world. Compass serves over 200 sponsors, from small biotech companies to the world's largest pharmaceutical companies, and has completed over 1,300 trials. With more than 300 years of combined clinical research experience, the Compass team focuses on neurodegenerative research and is renowned for its strength in enrolling specialty patient populations and completing advanced diagnostic procedures. For more information, please visit www.CompassResearch.com.

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 developing multiple precision diagnostic products and platforms including NAV4694, NAV5001, Manocept™ and RIGScan™ , to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and, ultimately, patient care. Lymphoseek® (technetium 99m tilmanocept) Injection, Navidea's first commercial product from the Manocept platform, 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] Parkinson's Disease Foundation. Statistics on Parkinson's: http://www.pdf.org/en/parkinson_statistics. Accessed on August 21, 2013.

Navidea Biopharmaceuticals
Brent Larson, 614-822-2330
Executive VP & CFO

or
Sharon Correia, 978-655-2686
Associate Director, Corporate Communications

Source: Navidea Biopharmaceuticals, Inc.