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Head-to-Head Study Comparing Navidea's AZD4694 to the Gold Standard for Imaging Beta Amyloid Protein Deposits Presented at Alzheimer's Association International Conference

Trial Examines AZD4694 Performance Characteristics and Blinded Reader Confidence when used as an Aid in Diagnosing Alzheimer's Disease

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a specialty pharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that clinical data from a head-to head study comparing its amyloid imaging candidate, AZD4694, to the benchmark amyloid imaging agent, ^{11}C-PiB (PiB), was presented at the Alzheimer's Association International Conference – AAIC in Vancouver, Canada by Professor Christopher Rowe, MD, FRACP, Director of the Department of Nuclear Medicine and Centre for PET at Austin Health, Melbourne, Australia.

In addition, on Friday, July 13, 2012, Navidea received approval for its Phase 2 AZD4694 protocol from the New England Institutional Review Board (IRB), a centralized IRB that oversees the approval of clinical protocols for investigational drugs for multiple research organizations. Trial enrollment is expected to commence in the coming months.

"We are extremely pleased with Dr. Rowe's encouraging findings demonstrating strong similarity of AZD4694 to the long-standing agent of choice, PiB. These and other data continue to confirm AZD4694's outstanding performance characteristics," commented Dr. Mark Pykett, Navidea's President and CEO. "We are also excited with the approval by the IRB of the Phase 2 protocol and look forward to rapidly commencing these studies as well as beginning Phase 3 clinical studies for this agent in early 2013."

"We are enthusiastic about the potential of this agent to facilitate research, diagnosis and therapeutic development for Alzheimer's disease," said Dr. Rowe. "As a second-generation beta amyloid tracer for PET scans, ^{18}F-AZD4694 combines the best features of the two current types of imaging agents -- the convenience of a fluorine-18 label, and favorable sensitivity, selectivity and decreased white matter binding which offers improved image clarity."

Dr. Rowe's talk was entitled, *"Head to head comparison of ^{11}C-PiB and ^{18}F-AZD4694 for Aβ imaging in ageing and dementia."* The presentation **highlighted new results from a blinded-reader analysis which examined imaging characteristics such as binding kinetics, standard uptake value ratios (SUVR) in three time intervals, and non-specific**

white-matter retention for these agents obtained in the same subjects. The two agents, ^{11}C-PiB and ^{18}F-AZD4694, were employed to sequentially image the brains of forty-five participants (25 healthy elderly controls, 10 subjects with Mild Cognitive Impairment, 7 subjects with probable Alzheimer's Disease and 3 subjects with fronto-temporal dementia). The mean age of the participant groups was about 74, except that the three fronto-temporal dementia patients averaged about 68 years old. Cognitive impairments in the patient groups showed mean scores on the Mini-Mental State Examination of 24 to 27 and were within the mild to moderate range.

As previously reported, quantitative measures, such as SUVR, of ^{18}F-AZD4694 **binding to cortical amyloid plaques are essentially identical to** ^{11}C-PiB. A very tight performance correlation was observed ($r=0.98$, $p<0.0001$; slope 0.95). Visually, images obtained in the same patient with the same scan times, the same data processing and the same display scales, were identical. **^{18}F-AZD4694 had comparable binding kinetics and dynamic range of SUVR to the benchmark ^{11}C-PiB as well as similar high values of cortex to white matter ratios.** Using the PiB as reference, the sensitivity, specificity, and overall accuracy within the 40- to 60-minute readings ranged from 94% to 98%. Additionally, confidence levels from the blinded readers averaged 93% using 40- to 60- minute readings, indicating a high degree of confidence in the interpretability of the images within this time range.

About AZD4694

AZD4694 is a Fluorine-18 labeled precision radiopharmaceutical candidate for use in the imaging and evaluation of patients with signs or symptoms of cognitive impairment such as AD. It binds to Beta-amyloid deposits in the brain that can then be imaged in positron emission tomography (PET) scans. Amyloid plaque pathology is a required feature of AD diagnosis and the presence of amyloid pathology is a supportive feature for diagnosis of probable AD.

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 three radiopharmaceutical agent platforms – Lymphoseek®, AZD4694 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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