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## Data on Navidea's AZD4694 Presented by the Banner Institute at the 6th Annual Human Amyloid Imaging Meeting (HAI)

**– Poster presentations highlight assessment of fibrillar Amyloid- $\beta$  (A $\beta$ ) deposition –**

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE Amex: NAVB) today announced that the Banner Alzheimer's Institute, Phoenix, AZ, made two presentations of results from an AstraZeneca-sponsored study on the assessment of Navidea's late-stage radiopharmaceutical imaging candidate, AZD4694, at the 6<sup>th</sup> Annual Human Amyloid Imaging Meeting (HAI), in Miami, FL. In December 2011, Navidea in-licensed the worldwide exclusive rights to AZD4694 from AstraZeneca, now being developed by Navidea as a radiopharmaceutical agent for the detection of cerebral amyloid in Alzheimer's disease (AD) patients.

The two poster presentations, titled, "[18F] AZD4694 PET Quantification for the Assessment of Fibrillar Amyloid- $\beta$  Deposition" and "[18F] AZD4694 PET in the Assessment of Fibrillar Amyloid- $\beta$  Deposition: Performance Characteristics," provide additional evidence that [18F] AZD4694 offers promise in the assessment of fibrillar Amyloid- $\beta$  (A $\beta$ ) deposition. Fibrillar Amyloid- $\beta$  PET ligands may provide useful tools in the scientific study, early detection, tracking and differential diagnosis of Alzheimer's disease and the evaluation of A $\beta$ -modifying treatments.

The findings in this study indicate that [18F] AZD4694 PET in the assessment of fibrillar A $\beta$  deposition in Alzheimer's disease is feasible and relatively straightforward with common analysis methodologies.

"We look forward to conducting additional studies to assess the safety and efficacy of this imaging agent as a potentially effective tool to aid the diagnosis of patients with Alzheimer's disease, a devastating disease that is reaching high levels in the United States and around the world," said Jessica Langbaum, staff scientist at the Banner Alzheimer's Institute.

The Banner Institute presentations at HAI described the use of [18F] AZD4694 in the examination of fibrillar A $\beta$  burden as an aid in the diagnosis of AD. The objective of the first part of the Banner study was to determine an analysis setting for examining the differential fibrillar A $\beta$  burden in three different groups: i) subjects with mild Alzheimer's dementia (n=8), ii) elderly healthy controls (oHC)(n=9), and iii) young normal controls who were not carriers of apolipoprotein E (APOE)  $\epsilon$ 4 (yNC)(n=4). Results indicate that individual images and the ability to distinguish between subject groups undergoing evaluation with AZD4694 were roughly comparable using two evaluation methods, Distribution Volume Ratio (Logan method and simplified Logan method) and Standard Uptake Ratio, used during various scan intervals, different cerebellar reference regions, and pre-injection versus post-emission

transmission scans.

In addition, differences between groups in the AZD4694 PET measurements were seen:

the 8 AD subjects had higher signals than the 9 oHC subjects presumably due to their higher amyloid level; the 8 AD subjects also had higher signals than the 4 yNC subjects; and the 9 oHC subjects had higher signals than the 4 yNC subjects.

The second part of the study used [18F] AZD4694 to characterize fibrillar A $\beta$  burden in subjects with probable mild Alzheimer's disease (n=8, 4 APOE  $\epsilon$ 4 carriers and 4 non-carriers), healthy elderly control subjects (n=9, 5 APOE  $\epsilon$ 4 carriers and 4 non-carriers) and healthy younger controls (n=5, all APOE  $\epsilon$ 4 non-carriers). The study objective was to assess group differences in fibrillar A $\beta$ , effect of apolipoprotein E (APO)  $\epsilon$ 4, and test-retest reliability (assessed using a second scan of AD and yNC subjects) of [18F] AZD4694. The results indicate that AZD4694 demonstrated rapid equilibrium and favorable Central Nervous System uptake/distribution, a relatively high specific signal-to-white matter background binding thus permitting reader-friendly images, the ability to distinguish between the participant groups, and high test-retest reliability as assessed in 3 AD and 4 yNC subjects.

While Navidea undertakes arrangements to commence its Phase III clinical program in early 2013, a number of additional ongoing and planned studies to build the requisite safety and training database will provide further information on AZD4694 during this year.

### **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 24,000,000 people worldwide. Currently in the U.S. alone, there are over 5 million Alzheimer's patients with estimates that by 2050, as many as 16 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 beta-amyloid *outside* nerve cells (neurons) in the brain and the accumulation of the protein tau *inside* neurons. Approximately 75 to 100 experimental therapies aimed at diagnosing, slowing or stopping the progression of Alzheimer's are now in human clinical trials.

### **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. Patients who are negative for amyloid pathology do not have AD.

### **About Navidea Biopharmaceuticals**

Navidea Biopharmaceuticals, Inc. (NYSE Amex: 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 presence and status 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](http://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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