

## Presentation Highlights Clinical Potential of Navidea Biopharmaceuticals' β-Amyloid Imaging Biomarker AZD4694

Results from Phase 1 and 2 clinical trials presented by AstraZeneca at 12th International Stockholm/Springfield Symposium on Advances in Alzheimer Therapy

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), today announced Phase 1 and Phase 2 clinical trials data from its radiopharmaceutical candidate, AZD4694 for the detection of amyloid in patients with Alzheimer's disease, were presented at the recent 12<sup>th</sup> International Stockholm/Springfield Symposium on Advances in Alzheimer Therapy meeting. The bi-annual conference focuses on pharmacological therapy in Alzheimer's disease (AD) and is organized by the Karolinska Institute, Sweden, University of Geneva, Switzerland, and Southern Illinois University, U.S. The three-day meeting featured world leaders in Alzheimer's disease innovation discussing new trial designs, animal models, and neuroimaging including PET and diagnostic recommendations. In December 2011 Navidea announced that it had in-licensed the worldwide rights for AZD4694 from AstraZeneca.

Dr. Zsolt Cselényi, M.D., Ph.D., Senior Research Physician at AstraZeneca AB presented a talk titled "Early clinical development of amyloid-beta specific PET radioligand [18F]AZD4694," during the Advances in Molecular Imaging in Alzheimer's disease meeting session. The presentation highlighted PET images pooled from Phase 1 and Phase 2 Karolinska Institute studies and a Phase 2 study from Banner Alzheimer's Institute (Phoenix, AZ). In this analysis, all PET images in the studies were processed from four distinct PET systems using vastly different resolutions. Comparisons of two quantitative approaches of peak-time and late-time standard uptake value ratios (SUVR) were evaluated.

Based on study findings, researchers reported that AZD4694 exhibited rapid kinetics and early peak equilibrium allowing for amyloid quantification using short acquisition protocols with simplified approaches. The agent also features other favorable performance characteristics, including high sensitivity and low non-target binding, facilitating high signal-to-noise ratios. Researchers further reported that AZD4694 peak-time SUVR offers an attractive option alongside late-time SUVR with similar sensitivity, higher cortex—to-white matter contrast and reliability. The characteristics of the agent appear to make it a strong biomarker candidate to facilitate detection of lower levels of amyloid and smaller changes in amyloid levels over time, as well as enhanced therapeutic drug development.

"We believe the pooled analysis results reported by AstraZeneca from the Karolinska and the Banner Alzheimer's Institute studies demonstrate that AZD4694 has greater sensitivity and better contrast that may enable earlier Alzheimer's disease identification and monitoring of disease progression over time," said Dr. Thomas Tulip, Executive Vice President and

Chief Business Officer, Navidea. "We look forward to AZD4694 Phase 3 study initiation in early 2013. Until then, we continue to support ongoing Phase 2 studies and are planning to commence additional Phase 2 studies later this year to further support the assessment of the safety and efficacy of AZD4694 as a potentially effective tool to aid the diagnosis in patients with Alzheimer's disease."

## **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 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<sup>(R)</sup>, AZD4694 and RIGScan<sup>TM</sup> - 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 <a href="http://www.navidea.com">http://www.navidea.com</a>.

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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