

January 15, 2013



# Navidea Biopharmaceuticals Announces Completion of Additional Fundamental Clinical Trial for Radiopharmaceutical Agent, NAV4694, in Alzheimer's Disease

**- The Company also obtains rights to two additional  $\beta$ -amyloid imaging agents from AstraZeneca -**

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced the completion of a study of its novel radiopharmaceutical NAV4694 as a biomarker for visual detection and quantification of cerebral  $\beta$ -amyloid in diagnosing Alzheimer's disease (AD). The study was designed and conducted by Navidea's partner, AstraZeneca, to assess the effects of various mass amounts of AZD4694 (NAV4694) on safety and the efficacy of Positron Emission Tomography (PET) scanning in subjects with AD and in healthy volunteers (HVs). Evaluations were completed on the effects of two mass doses of the radioligand on binding parameters and overall image quality. These endpoints are typical and important requirements of drug registration dossiers filed with regulatory authorities for approval of diagnostic agents.

The completed trial was an open-label, non-randomized, multi-center, PET study in a total of sixteen individuals (8 with mild to moderate AD and 8 elderly HVs) each imaged on two PET systems at Karolinska Institutet sites in Stockholm, Sweden. The study included elderly HVs to demonstrate that no unexpected tracer mass effects of AZD4694 (NAV4694) in subjects with low or no cerebral  $\beta$ -amyloid occur; to compare imaging parameters from healthy, non-AD subjects with those from subjects with AD; and to extend the safety database.

"We are very pleased to have completed this study addressing some of the fundamental requirements of diagnostic imaging agents seeking approval. We continue to make exciting progress with NAV4694, which has demonstrated important performance characteristics that we believe position it as a true 'best-in-class' second generation agent to aid in the diagnosis of Alzheimer's disease," said Cornelia Reininger, MD, PhD, Navidea's Chief Medical Officer. "As previously reported in other Phase 2 studies, NAV4694 exhibits the strengths of  $^{11}\text{C}$  PIB, the benchmark amyloid imaging agent, but, as the agent is radio-labeled with  $^{18}\text{F}$ , has distribution characteristics that make it more practical to use. The data from these studies suggest that NAV4694 shows favorable sensitivity, specificity, rapid brain uptake yet decreased white-matter uptake which affords improved image clarity."

Dr. Reininger added, "We remain very enthusiastic about the potential of NAV4694 to advance clinical capabilities in diagnostic and therapeutic development for Alzheimer's disease. Results from this study are expected to be reported at the 2013 Annual Meeting of

the Society of Nuclear Medicine and Molecular Imaging. We look forward to initiation of the NAV4694 Phase 3 study in 2013.”

Navidea is also announcing that it has expanded its relationship with AstraZeneca and obtained rights to two additional  $\beta$ -amyloid imaging agents. AZD2184 and AZD2995 expand Navidea’s intellectual property portfolio and are positioned for research use to further establish its leadership within the AD community in basic science research. AZD2184 and AZD2995 are  $^{11}\text{C}$  Positron Emission Tomography (PET) radioligand tracers discovered by AstraZeneca in collaboration with Karolinska Institutet in Stockholm. AstraZeneca entered the agreement to ensure that the compounds are available to KOLs and academic centers. Both parties believe that these agents may serve as useful laboratory tools to support additional investigation of Alzheimer’s disease. Financial terms related to the granting of the additional rights were not disclosed as they were not material.

### **About NAV4694**

NAV4694 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. AZD4694 was licensed from AstraZeneca in December 2011.

### **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<sup>®</sup>, NAV4694, NAV5001 and RIGScan<sup>™</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 [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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Source: Navidea Biopharmaceuticals, Inc.