Navidea Announces Data Presentations at 2013 Annual Meeting of the Society of Nuclear Medicine and Molecular Imaging (SNMMI)

Fourteen presentations highlight results from Lymphoseek® and NAV4694 clinical trials

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced that data from its Lymphoseek® (technetium Tc 99m tilmanocept) Injection and NAV4694 studies are being presented at the 2013 Annual Meeting of the Society of Nuclear Medicine and Molecular Imaging (SNMMI) to be held June 8-12, 2013 in Vancouver, Canada. In addition to the ten oral and poster presentations highlighting both the comparative performance of Lymphoseek against commonly-used non-receptor targeted colloidal materials as well as the results demonstrating the efficacy of lymphatic mapping in breast, melanoma and head and neck cancers, there will also be four oral and poster presentations focused on Navidea’s β-amyloid PET imaging agent, NAV4694, that will reveal performance and comparative results from clinical studies in Alzheimer’s disease.

“We are honored to have these data showcased at the world’s premier educational and networking event for molecular imaging and nuclear medicine. These peer-reviewed presentations represent the growing body of clinical experience supporting both our recently launched lymphatic mapping agent, Lymphoseek, and the potential of NAV4694 as a diagnostic aid in Alzheimer’s disease and cognitive impairment,” said Dr. Mark Pykett, CEO of Navidea. “We are proud to have what we believe is the deepest late-stage radiopharmaceutical pipeline in the industry and remain committed to developing precision diagnostics that help identify the presence and status of disease enabling better diagnostic accuracy, clinical decision-making and ultimately patient care.”

Notable data from Navidea and its collaborators being presented at SNMMI 2013 include:

**Lymphoseek (tilmanocept)**

<p>| Presentation Title | 99m Tc]Tilmanocept identifies more positive nodes using fewer sentinel lymph nodes compared to [99mTc] sulfur colloid in early stage breast cancer patients |</p>
<table>
<thead>
<tr>
<th>Author:</th>
<th>Jennifer Baker, MD, Surgery, University of California San Diego et al</th>
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<tbody>
<tr>
<td><strong>Poster Title:</strong></td>
<td>Receptor-seeking near-infrared radiopharmaceutical IRDye800CW - tilmanocept for multi-modality sentinel lymph node imaging</td>
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<tr>
<td><strong>Author:</strong></td>
<td>Zhengtao Qin, PhD, Department of Chemistry, University of California San Diego et al</td>
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| **Presentation Title:** | Comparison of key sentinel node biopsy parameters for 99mTc-tilmanocept (TcTM) and 99mTc-sulfur colloid (TcSC) in breast cancer |
| **Author:** | Stephen Povoski, MD, Ohio State University Wexner Medical Center et al |

| **Presentation Title:** | Intraoperative lymphatic mapping efficacy of 99mTc-tilmanocept (TcTM) does not change over time post-injection relative to time of surgery |
| **Author:** | James O'Donnell, MD, Case Western University Hospitals et al |

| **Poster Title:** | Comparison of key sentinel node biopsy parameters for 99mTc-tilmanocept and 99mTc-sulfur colloid in melanoma |
| **Author:** | Vernon Sondak, MD, H. Lee Moffitt Cancer Center et al |

| **Poster Title:** | Dynamic SPECT/CT quantification of sentinel lymph node uptake & injection site clearance (ISC): Pilot study in intraoperative lymphatic mapping for breast cancer |
| **Author:** | Nathan C. Hall, MD PhD, The Ohio State University et al |

| **Poster Title:** | Bone marrow time-activity curves of [68Ga]-tilmanocept exhibit molar dose-dependency |
| **Author:** | Carl Hoh, MD, Radiology, University of California San Diego et al |

| **Presentation Title:** | Sentinel lymph node mapping via fluorescence imaging of a multi-modal receptor-binding probe |
| **Author:** | David Vera, PhD, UCSD and UCSD InVivo Cancer and Molecular Imaging et al |

| **Presentation Title:** | Dynamics of 99mTc-tilmanocept in intraoperative lymphatic mapping |
| **Author:** | Frederick Cope, PhD, Navidea Biopharmaceuticals, Inc. et al |

| **Presentation Title:** | Comparison of false negative rate (FNR) & overall accuracy (AC) of sentinel lymph node biopsy (SLNB) in phase 3 99mTc-tilmanocept (TcTM) vs ACOSOG Z-0360 99mTc-sulfur colloid (TcSC) in head/neck squamous cell cancer (SCC) |
| **Author:** | Francisco J. Civantos, MD, FACS, University of Miami Cancer Center et al |
NAV4694

**Presentation Title:** Emerging Technologies Session: Neurodegenerative Imaging

**NAV4694: A PET Biomarker for Brain Amyloid**

**Author:** Connie Reininger, MD, PhD, Navidea Biopharmaceuticals, Inc.

**Presentation Title:** Visual and semiquantitative validation of early and late Aβ imaging approaches using 18F-NAV4694

**Author:** Christopher Rowe, PhD, Centre for PET, Austin Health, Melbourne, Australia et al

**Poster Title:** White matter segmentation analyses for assessing cortical SUVr in Alzheimer's using the novel PET amyloid tracer 18F NAV4694

**Author:** John Seibyl, MD, Institute for Neurodegenerative Disorders et al

**Poster Title:** Effect of ligand mass dose on binding of the β-amyloid specific radioligand [18F]AZD4694 (NAV4694)

**Author:** Zsolt Cselényi, PhD, Karolinska Institutet, AstraZeneca Translational Science Center et al

Full session details, data presentation listings and abstracts at SNMMI can be found through the Annual Meeting website at [http://interactive.snm.org/index.cfm?pageID=12252](http://interactive.snm.org/index.cfm?pageID=12252).

**About Lymphoseek®**

Lymphoseek® (technetium Tc 99m tilmanocept) Injection is a novel, receptor-targeted, small-molecule radiopharmaceutical used in lymphatic mapping procedures that are performed to help in the diagnostic evaluation of potential cancer spread for patients with breast cancer and melanoma. Lymphoseek is designed to identify the lymph nodes that drain from a primary tumor, which have the highest probability of harboring cancer. Lymphoseek was approved by the U.S. Food and Drug Administration in March, 2013 for use in lymphatic mapping to assist in the localization of lymph nodes draining a primary tumor in patients with breast cancer or melanoma. The Company anticipates continuing development of Lymphoseek into other solid tumor areas that may include head and neck cancers, prostate cancer, thyroid cancer, lung/bronchus cancers, colorectal cancer and others.

Accurate diagnostic evaluation of cancer is critical, as it guides therapy decisions and determines patient prognosis and risk of recurrence. According to the American Cancer Society, approximately 232,000 new cases of breast cancer, 77,000 new cases of...
melanoma and 67,000 new cases of head and neck/oral cancer are expected to be
diagnosed in the United States in 2013.

About NAV4694

NAV4694 is a Fluorine-18 labeled precision radiopharmaceutical candidate intended for
use in Positron Emission Tomography (PET) imaging and evaluation of patients with signs
or symptoms of cognitive impairment such as Alzheimer’s disease (AD). NAV4694 binds
to β-Amyloid deposits in the brain that can then be imaged in scans. β-Amyloid plaque
pathology is widely used in the diagnosis of AD. The ability of NAV4694 imaging to display
amyloid plaque pathology may enable earlier identification of AD and improve monitoring
of disease progression and interpretation of brain scan images. Navidea plans for a Phase
3 trial of NAV4694 to begin in 2013.

AD is a progressive and fatal neurodegenerative disease. β-Amyloid imaging has the
potential to play an increasingly important role in clinical practice as revised criteria for the
diagnosis of probable AD allow for earlier diagnosis and therapeutic intervention.
Alzheimer’s Disease International estimated in 2010 that there were 36 million people
living with all forms of dementia including 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 four radiopharmaceutical
agent platforms – Lymphoseek®, NAV4694, NAV5001 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

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.