April 3, 2012

FDA Extends PDUFA Date for Lymphoseek® by Three Months

Lymphoseek Remains on Track for First-Cycle Review

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE Amex: NAVB) today announced that yesterday it received notification from the United States Food and Drug Administration (FDA) that the Prescription Drug User Fee Act (PDUFA) date for 99m-Tc-Tilmanocept (Lymphoseek®), has been modified to September 10, 2012, a 90-day extension from the initial PDUFA date of June 10th. Lymphoseek is an investigational, proprietary radioactive tracing agent for lymphatic mapping and lymphoscintigraphy.

As part of its ongoing support of the Lymphoseek NDA review, on March 30, 2012, the Company provided as requested by the Agency, updated chemistry, manufacturing and control information related to one of several drug analytical assays. As this information was submitted within the 90-day period prior to the PDUFA date, on April 2nd, FDA at its option elected to extend the review period by 90 days to complete a first-cycle evaluation. Neither this FDA decision nor the NDA review-to-date has raised questions on Lymphoseek's safety or efficacy. The PDUFA date extension does not pertain to the Company's ongoing head and neck cancer clinical trial or to the recently announced comparative analysis of Lymphoseek to sulfur colloid.

"We have submitted the information requested by the FDA in support of a first-cycle review of the Lymphoseek NDA," said Mark Pykett, Navidea President and CEO. "Our focus continues to be on supporting the FDA review and preparing for anticipated market introduction of Lymphoseek. All of the clinical data we have generated for Lymphoseek to date support a clear safety and efficacy profile, which we believe holds value to patients and their physicians."

About Lymphoseek

Lymphoseek is a proprietary radioactive tracing agent being developed for use in connection with gamma detection devices in pre-operative lymphoscintigraphy imaging and in a surgical procedure known as Intraoperative Lymphatic Mapping. Lymphoseek works by binding to a specific receptor found on the surface of dendritic cells and macrophages, which reside in high concentration in lymph nodes. This receptor-targeted property of Lymphoseek enables it to attach to and remain within lymph nodes.

Two Phase 3 multi-center clinical trials (www.clinicaltrials.gov, trial registration numbers NCT00671918 and NCT01106040) for Lymphoseek in patients with breast cancer or melanoma have concluded. A third Phase 3 clinical study to evaluate the efficacy of Lymphoseek as a sentinel lymph node tracing agent in patients with head and neck squamous cell carcinoma is currently ongoing (www.clinicaltrials.gov, trial registration

number NCT00911326). To date Lymphoseek is the first and only receptor-targeted agent developed specifically for ILM.

About the Lymphoseek NDA Submission

The Lymphoseek NDA submitted by the Company in August 2011 includes results from two complete Phase 3 studies of Lymphoseek, NEO3-05 and NEO3-09, performed in patients with either breast cancer or melanoma. The primary endpoint for both the NEO3-05 and NEO3-09 studies was the concordance (or the rate of agreement) on a lymph node count basis of Lymphoseek with vital blue dye, a long-standing, FDA-approved, on-label agent for lymphatic mapping and appropriate "Truth Standard" comparator for registration purposes. In both of the Phase 3 studies (NEO3-05, NEO3-09), the concordance of Lymphoseek to vital blue dye was highly statistically significant ($p<0.0001$). Lymphoseek met all primary and secondary endpoints across both studies. Secondary endpoints were also assessed, including the false negative rate (or failed detection rate) of Lymphoseek versus vital blue dye. This analysis evaluated the ability of vital blue dye and Lymphoseek to detect lymph nodes that potentially contained cancer cells, as determined by pathology evaluation. In both studies combined, vital blue dye exhibited a failed lymph node detection rate of more than 20%, whereas Lymphoseek showed a failed lymph node detection rate of approximately 1%, or twenty-fold lower than vital blue dye, a difference that was also highly statistically significant ($p<0.002$). Because the key objective of performing ILM is to potentially identify cancer cells when they are present in lymph nodes, reduction of the failed lymph node detection rate is important.

In more than 500 subjects receiving Lymphoseek to date, including those studied as a part of the NEO3-05 and NEO3-09 studies, no drug-related serious adverse events or clinically significant drug-related adverse events have been reported.

About Navidea

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.

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.