Navidea Awarded SBIR Grant from the NIH for Development of Radio-Immuno-Guided Surgery (RIGS) Agent Aimed at Detecting Metastatic Cancer

The Associated Press

DUBLIN, Ohio--(BUSINESS WIRE)--Sep 20, 2012--Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced the receipt of a Small Business Innovation Research (SBIR) grant from the National Cancer Institute (NCI), National Institutes of Health (NIH), to fund the development of the Company's radio-immuno-guided surgery monoclonal antibody targeting agent for use in detecting metastatic sites in colorectal cancer. The SBIR grant has the potential for grant money up to a total of $1.5M over three years if fully funded. The first-year Phase I funding of $315,000, which has already been approved, is expected to enable Navidea to complete preclinical bridging activities using a RIGS tumor-antigen-targeted monoclonal antibody and prepare a standardization clinical trial protocol. Second and third year (Phase II) funding of up to $1.2M is contingent upon meeting certain Phase I success criteria, including Institutional Review Board (IRB) approval of the clinical trial protocol.

"We are pleased that NIH/NCI has recognized the potential value for Navidea’s RIGS agent to significantly benefit surgeons in effectively locating cancerous tissues during surgery and enabling their more thorough surgical removal for better patient outcomes. We appreciate NCI’s support as we complete these important preclinical studies and prepare for re-initiation of human clinical trials," said Mark Pykett, V.M.D., Ph.D., President and CEO of Navidea. "The development of our RIGS monoclonal antibody agent represents another clinical advancement of Navidea’s pipeline of innovative precision diagnostic products, including Lymphoseek ® and NAV4694, which target devastating oncologic and neurologic diseases." About the RIGS Monoclonal Antibody Targeting Agent The RIGS targeting agent is an investigational, tumor-specific, radio-labeled monoclonal antibody. It may be used during surgery to identify cancerous tissue undetectable by traditional diagnostic and intraoperative techniques. The RIGS monoclonal antibody agent may enable more effective surgeries caused by metastasized colorectal cancers leading to improved patient survival.

Before surgery, a cancer patient is injected with the RIGS targeting agent which circulates throughout the patient’s body and binds specifically to cancer cell antigens or receptors. Concentrations of the RIGS targeting agent within affected tissue are then detected using a gamma probe and direct the surgeon to targeted tissue for removal.

About Colorectal Cancer and Metastatic Disease With nearly 140,000 new diagnoses

and 50,000 deaths each year in the U.S., adenocarcinomas of the colon and rectum are a common and deadly form of cancer. When patients are first diagnosed with these diseases, they undergo surgeries to remove their tumors. Colon and rectal (colorectal) cancers, like nearly all forms of cancer, are insidious in that they can spread or metastasize from their primary sites of origin to multiple locations throughout the body. Patients who eventually succumb to colorectal cancer are killed by the uncontrolled growth of these metastatic tumors. It is well established that for colorectal cancers the most common site to which the cancer will spread first is the liver. Frequently, it is still possible to cure or dramatically extend the life of a patient with liver metastases using surgery if their cancer has not yet spread beyond the liver. About one third of colorectal cancer patients undergo surgeries to remove liver metastases.

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, CFT and RIGScan TM – 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.

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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