November 26, 2013

Navidea to Collaborate with University of Alabama–Birmingham on Clinical Study Evaluating the RIGS™ Monoclonal Antibody Targeting Agent

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAVB), a biopharmaceutical company focused on precision diagnostic radiopharmaceuticals, today announced it will collaborate with investigators at the University of Alabama at Birmingham (UAB) on a clinical study to evaluate the safety and activity of a radiolabeled, humanized monoclonal antibody (Mab) from its RIGS™ Monoclonal Antibody Targeting technology. The study will evaluate up to 20 patients with colorectal cancer (CRC) by administering the RIGS tumor-specific radiolabeled, CH2 domain-deleted, anti-TAG-72 Mab-targeting agent and assessing by SPECT/CT imaging for the presence of liver metastasis. The co-principle investigators for the study are Andres Forero, MD, the O'Neal-Sokol Breast Cancer Research Foundation of Alabama Endowed Professorship, Director, Protocol/Data Management Shared Facility, and Co-Leader, Experimental Therapeutics, UAB Comprehensive Cancer Center; Kurt Zinn, DVM, MS, PhD, Director, Advanced Medical Imaging Research, UAB; and Janis P. O'Malley, MD, Director, Division of Molecular Imaging and Therapeutics, and Professor of Radiology, UAB School of Medicine. Investigators at UAB have published extensively on the use of TAG-72 targeted monoclonal antibodies in the cancer setting.

"The detection of metastasis of colorectal cancer to the liver has had less than acceptable sensitivity and low specificity using traditional CT. There is the need to find better modalities to evaluate the liver at the time of the initial diagnosis of CRC," commented Dr. Forero. "We are looking forward to working with Navidea to evaluate this tumor-specific imaging agent that may benefit surgeons in effectively locating cancerous tissues leading to better patient outcomes."

The study is to be funded in part through the Company's Small Business Innovation Research (SBIR) grant from the National Cancer Institute (NCI), National Institutes of Health (NIH) announced in 2012. 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, focused on completing preclinical bridging activities using the CH2 domain-deleted, anti-TAG-72 Mab and preparing a standardized clinical trial protocol. Phase II funding of up to $1.2M will be used in support the clinical study and is contingent upon meeting certain Phase I success criteria, including Institutional Review Board (IRB) approval of the clinical trial protocol. Commencement of the clinical study is also contingent upon completing certain antibody stability and quality tests currently in process.

"We are excited to work with UAB as we re-initiate human clinical trials with our RIGS agent,"

said Frederick Cope, PhD, FACN, Senior Vice President and Chief Scientific Officer at Navidea. “We are also pleased with the current and potential future support of the NCI/NIH grant funding as we advance development efforts in this important technology.”

About RIGS™ Monoclonal Antibody Targeting

RIGS (radio-immuno-guided surgery) monoclonal antibody targeting technology includes an investigational, tumor-specific, radiolabeled humanized monoclonal antibody (CH2 Domain-Deleted, Anti-TAG-72). It may be useful prior to, during, or after surgery to identify cancerous tissue undetectable by traditional diagnostic and intraoperative techniques. The RIGS agent may enable more effective detection and surgical intervention of colorectal cancers, and potentially other cancers, leading to improved patient management and survival. By binding specifically to the target TAG-72 cancer antigen, the RIGS agent accumulates within affected tissue and is then detected by imaging or a gamma probe.

About TAG-72

The tumor-associated glycoprotein (TAG-72) is a target for detection of the spread of CRC to the liver. TAG-72 is expressed on the surface of a wide range of carcinomas and prompted the development of antibodies to TAG-72 for investigation in the diagnosis and treatment of carcinomas.

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 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 developing multiple precision diagnostic products and platforms including NAV4694, NAV5001, Manocept™ and RIGScan™ , to help identify the sites and pathways of undetected disease and enable better diagnostic accuracy, clinical decision-making and, ultimately, patient care. Lymphoseek® (technetium 99m tilmanocept) Injection, Navidea’s first commercial product from the Manocept platform, was approved by the FDA in March 2013. 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.

Navidea Biopharmaceuticals
Brent Larson, Executive VP & CFO, 614-822-2330
or
Sharon Correia, Associate Director, Corporate Communications, 978-655-2686

Source: Navidea Biopharmaceuticals, Inc.