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# **Navidea to Collaborate with University of California–San Francisco on Clinical Study Evaluating Manocept™ Platform Imaging Agent in Kaposi Sarcoma (KS) Patients**

**- Investigator-Initiated Study will evaluate KS lesions using technetium-labeled tilmanocept imaging -**

**- Supporting results from proof-of-concept study in KS tissue reported at an international conference on AIDS -**

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 California, San Francisco (USCF), on a clinical study to evaluate, for the first time, the use and performance of technetium–labeled tilmanocept in patients with Kaposi Sarcoma (KS). The investigator–initiated study will evaluate HIV patients with various stages of KS who will be administered <sup>99m</sup>Tc-tilmanocept and assessed by SPECT imaging for localization of KS lesions and possible identification of KS disease spread. Co-primary investigators are Michael S. McGrath, MD, PhD, Professor, Departments of Laboratory Medicine, Pathology, and Medicine, UCSF, and Toby Maurer, MD, Dermatologist, UCSF Lakeshore Family Medicine Center.

“Kaposi sarcoma not only affects skin but in more advanced states involves other organs and tissues, including lymph nodes. Attempts to confirm KS involvement in other tissues to determine if and where the tumor has spread have generally been problematic, so patient staging and treatment regimens may not be optimally managed,” commented Dr. McGrath. “The receptor-targeting properties and strong performance in malignancies such as melanoma and breast cancer indicate that tilmanocept and other Manocept-derived agents which specifically target the CD206 mannose receptor are potentially potent tools for addressing unmet needs in this area such as identifying, staging and assessing disease activity.”

Navidea also announced that results from a study of Kaposi sarcoma (KS) tissue, using a novel fluorescent imaging agent from the Company’s Manocept™ Platform, were presented at the 14th International Conference on Malignancies in AIDS and Other Acquired Immunodeficiencies (ICMAOI) by Dr. McGrath this week at the National Institutes of Health in Bethesda, Maryland.

The study presentation, “*Tilmanocept, a labeled ligand for macrophage mannose receptor (CD206) may allow imaging of Kaposi’s sarcoma spindle cells and tumor associated*

*macrophages*,” was designed to assess the feasibility of a Manocept imaging agent for specific KS tumor imaging. The results indicate that in 66 evaluable cases, the presence of CD206, the mannose receptor, was confirmed on tumor-associated macrophages (TAMs) as well as a majority of KS tumor cells and that CD206 was the most prevalent antigen for both KS tumor spindle cells and TAMs. The authors concluded the results indicate that the agent may allow effective imaging of KS involved tissues and nodes including potential visceral sites of disease. Attributes of the fluorescent Cy3-tilmanocept agent were recently presented in a [special supplement](#) to the journal Nature entitled [Nature Outlook: Medical Imaging](#).

“This conference presentation further emphasized the potential of our Manocept platform into therapeutic areas where there is medical need for innovative precision diagnostics in the quest for better patient outcomes,” said Frederick Cope, PhD, FACN, Senior Vice President and Chief Scientific Officer at Navidea. “These newly developed data suggest that our Manocept platform represents an opportunity to exploit the CD206-targeting mechanism underlying the robust, purpose-built drug design of our approved lymphatic mapping agent. With the announcement of our exciting UCSF clinical collaboration, we intend to continue to evaluate emerging data in KS and will further explore other disease states to refine our areas of focus and capitalize on this innovative platform.”

#### **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](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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