

September 22, 2016



# Navidea Achieves \$1 Million in Lymphoseek® Commercial Milestones

***- Navidea earns a \$500,000 payment from Cardinal Health, Inc. with the sale of the 100,000<sup>th</sup> Lymphoseek dose -***

***- Navidea to receive \$500,000 payment from SpePharm AG, an affiliate of Norgine, B.V., for EMA approval of Lymphoseek single dose vial -***

DUBLIN, Ohio--(BUSINESS WIRE)-- Navidea Biopharmaceuticals, Inc. (NYSE MKT:NAV B) has announced it will receive payments totaling \$1 million from two recently achieved Lymphoseek® commercial milestones under its distribution agreements with U.S. partner Cardinal Health, Inc. (Cardinal) and European partner SpePharm AG, an affiliate of Norgine B.V. (Norgine). Navidea will collect a \$500,000 milestone payment from Cardinal based on the sale of a 100,000<sup>th</sup> patient dose of Lymphoseek (technetium Tc 99m tilmanocept) injection since launch. The Company will also receive a \$500,000 payment from Norgine resulting from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) positive opinion for the Lymphoseek 50 microgram kit for radiopharmaceutical preparation, a reduced-mass, single-dose vial appropriate for the radiopharmaceutical distribution model in Europe.

"We are pleased with the meaningful progress that Navidea and its partners have made in our commercial distribution efforts in both the U.S. and Europe," said Jed Latkin, interim Chief Operating Officer and Chief Financial Officer. "These milestones reflect the growing acceptance of Lymphoseek in the U.S. for improving the outcomes in patients with melanoma, breast and oral cavity cancers and signal the expected European launch of Lymphoseek in Q42016."

Lymphoseek is approved in the U.S. by the U.S. Food and Drug Administration (FDA) for use in lymphatic mapping to locate lymph nodes draining a primary tumor site in patients with solid tumors for which this procedure is a component of intraoperative management and for guiding Sentinel Lymph Node Biopsy (SLNB) using a handheld gamma counter in patients with node negative squamous cell carcinoma of the oral cavity, breast cancer or melanoma. Lymphoseek is indicated in the EU for imaging and intraoperative detection of sentinel lymph nodes draining a primary tumor in adult patients with breast cancer, melanoma, or localized squamous cell carcinoma of the oral cavity.<sup>1</sup>

## **About Navidea**

Navidea Biopharmaceuticals, Inc. (NYSE MKT: NAV B) is a biopharmaceutical company focused on the development and commercialization of precision immunodiagnostic agents and immunotherapeutics. Navidea is developing multiple precision-targeted products and platforms including Manocept™ and NAV4694 to help identify the sites and pathways of

undetected disease and enable better diagnostic accuracy, clinical decision-making, targeted treatment and, ultimately, patient care. Lymphoseek® (technetium Tc 99m tilmanocept) injection, Navidea's first commercial product from the Manocept platform, was approved by the FDA in March 2013 and in Europe in November 2014. The development activities of the Manocept immunotherapeutic platform will be conducted by Navidea in conjunction with its subsidiary, Macrophage Therapeutics. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel products and advancing the Company's pipeline through 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, our ability to repay our debt, the outcome of the CRG litigation, 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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## References

<sup>1</sup> European Medicines Agency LYMPHOSEEK approval 2014.  
[http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002085/human\\_med\\_001827.jsp&mid=WC0b01ac05](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002085/human_med_001827.jsp&mid=WC0b01ac05)  
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