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# **Xenetic Biosciences Announces FDA Acceptance of Investigational New Drug Application to Initiate Phase 2 Clinical Trial of Virexxa® in Endometrial Cancer**

LEXINGTON, Mass.-- [Xenetic Biosciences, Inc.](#) (OTCQB: XBIO) ("Xenetic" or the "Company"), a biopharmaceutical company developing next-generation biologic drugs and novel orphan oncology therapeutics, announced today that an Investigational New Drug (IND) application for the Company's product candidate, Virexxa® (sodium cridanmod), has been allowed to proceed by the U.S. Food and Drug Administration (FDA). This enables Xenetic to initiate a Phase 2 clinical study of Virexxa in conjunction with progestin therapy for the treatment of endometrial cancer in women with recurrent or persistent disease who have failed progestin monotherapy. The primary objective of the study is to assess the anti-tumor activity of Virexxa. Secondary objectives include assessment of additional efficacy, pharmacokinetic and safety/tolerability parameters. Further translational objectives are to observe the effect of Virexxa in combination with progestins, on the levels of progesterone receptor (PrR) and activated progesterone receptors (APrR) in tumor tissues.

"This IND clearance enables us to proceed with our Phase 2 study in endometrial cancer and represents a major step forward in our clinical development of Virexxa," stated Scott Maguire, CEO. "We believe Virexxa® to be a next-generation therapeutic that has the potential to provide women with no additional treatment options a novel and effective therapy."

Endometrial cancer is the most common malignancy of the female genital tract and represents a major health concern, as overall five-year survival rates have not improved over the past three decades. Annually in the United States, an estimated 60,050 patients are diagnosed with endometrial cancer and 10,470 deaths occur from this disease, representing 1.8% of all cancer deaths in the US. The incidence of endometrial cancer is on the rise with a lifetime risk of approximately 3% while the disease-specific mortality of endometrial carcinoma has been rising in the last 25 years. Endometrial cancer patients whose tumors no longer express progesterone receptors are not candidates for progestin-based therapy. Patients who fail monotherapy with progestins have no additional treatment options. Virexxa may improve sensitivity to progestin therapy in subjects with advanced or recurrent PrR-negative tumors.

## **About Virexxa®**

Virexxa is a small-molecule immunomodulator and interferon inducer which, in preliminary studies, has been shown to increase progesterone receptor (PrR) expression in endometrial tissue. Restoration of PrR expression may re-sensitize endometrial tumor tissue to progestin

therapy in previously unresponsive tumors.

Virexxa is currently being studied in an ongoing Phase 2 multi-national study enrolling 58 subjects with documented evidence of progesterone receptor negative (PrR-negative) endometrial cancer as determined by tumor biopsy. This study is being conducted in conjunction with Pharmsynthez PJSC (St. Petersburg Russia) and its subsidiary AS Kevelt (Tallinn, Estonia). For more information on this Phase 2 study of Virexxa for the treatment of PrR-negative endometrial cancer, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and reference Identifier NCT02064725.

### **About Xenetic Biosciences**

Xenetic Biosciences, Inc. is a biopharmaceutical company developing next-generation biologic drugs and novel oncology therapeutics. Xenetic's proprietary drug technology platforms include PolyXen<sup>®</sup>, designed to develop next generation biologic drugs by extending the efficacy, safety and half-life of biologic drugs.

Xenetic's lead product candidates include ErepoXen<sup>™</sup>, a polysialylated form of erythropoietin for the treatment of anemia in pre-dialysis patients with chronic kidney disease, and FDA orphan designated oncology therapeutics Virexxa<sup>®</sup> and Oncohist<sup>™</sup> for the treatment of progesterone receptor negative endometrial cancer and refractory Acute Myeloid Leukemia.

Xenetic is also working together with Shire plc (formerly Baxalta Incorporated, a spinoff of the biopharmaceuticals business from Baxter Healthcare SA and Baxter Healthcare Corporation) to develop a novel series of polysialylated blood coagulation factors, including a next generation Factor VIII. This collaboration relies on Xenetic's PolyXen technology to conjugate polysialic acid ("PSA") to therapeutic blood-clotting factors, with the goal of improving the pharmacokinetic profile and extending the active life of these biologic molecules. Shire is one of the Company's largest shareholders having invested \$10M in the common stock of the Company during 2014. The agreement is an exclusive research, development and license agreement which grants Shire a worldwide, exclusive, royalty-bearing license to Xenetic's PSA patented and proprietary technology in combination with Shire's proprietary molecules designed for the treatment of blood and bleeding disorders. Under the agreement, Xenetic may receive regulatory and sales target payments for total potential milestone receipts of up to \$100 million plus royalties on sales.

In addition, Xenetic is developing a broad pipeline of clinical candidates for next generation biologics and novel oncology therapeutics in a number of orphan disease indications. For more information, please visit the company's website at [www.xeneticbio.com](http://www.xeneticbio.com) and connect on [Twitter](#), [LinkedIn](#), [Facebook](#) and [Google+](#).

### **Forward-Looking Statements**

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding expected benefits of NGS cancer panels, the ability to accurately determine the heritable factors increasing the risk of cancer, permitting tailored treatment, screening and prevention of cancer in patients, as well as other non-historical statements

about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described in our filings with the Securities and Exchange Commission, as well as the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

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