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Xenetic Biosciences Commences Patient Enrollment in Phase 2 Study Evaluating XBIO-101 in Conjunction with Progestin Therapy for the Treatment of Endometrial Cancer

– Patient dosing expected in Q3 2017 –

LEXINGTON, Mass.--(BUSINESS WIRE)-- [Xenetic Biosciences, Inc.](#) (NASDAQ: XBIO) ("Xenetic" or the "Company"), a clinical-stage biopharmaceutical company focused on the discovery, research and development of next-generation biologic drugs and novel orphan oncology therapeutics, today announced that patient enrollment has commenced in its Phase 2 clinical study of [XBIO-101](#) (sodium cridanomod) in conjunction with progestin therapy for the treatment of endometrial cancer, in a population of patients who have either failed progestin monotherapy or who have been identified as having progesterone receptor negative ("PrR-") tumors.

XBIO-101, Xenetic's lead product candidate in development, is a small-molecule immunomodulator and interferon inducer which, in preliminary studies, has been shown to increase progesterone receptor ("PrR") expression in endometrial tumor tissue.

"We are very pleased to commence patient enrollment in this Phase 2 study with our flagship product candidate and believe this trial is designed to provide greater understanding of XBIO-101 for the treatment of progestin resistant endometrial cancer," stated [M. Scott Maguire, Xenetic's CEO](#). "Based on these preliminary findings, we believe that XBIO-101 has the potential to increase the expression of PrR on endometrial tumors thereby making them more responsive to treatment with traditional progestin therapy, and ultimately provide a much-needed solution for late stage endometrial cancer patients."

The primary objective of the open-label, multi-center, single-arm, two-period Phase 2 study is to assess the antitumor activity of XBIO-101 in conjunction with progestin therapy as measured by Overall Disease Control Rate ("ODCR") in women with recurrent or persistent endometrial carcinoma not amenable to surgical treatment or radiotherapy who have either failed progestin monotherapy or who have been identified as PrR-. Secondary objectives include assessments of efficacy and safety/tolerability parameters.

The study is expected to enroll a total of 72 women with recurrent or persistent endometrial cancer not amenable to surgical treatment or radiotherapy but suitable to be treated with progestins. All subjects determined to be PrR- at screening, as well as those subjects who experience disease progression after at least 4 weeks of progestin monotherapy, will receive

XBIO-101 in combination with continued progestin treatment. Subjects will receive treatment until disease progression as defined according to RECIST 1.1 criteria.

For more information about the Phase 2 clinical study of XBIO-101 in conjunction with progestin therapy for the treatment of endometrial cancer, please visit clinicaltrials.gov and reference Identifier NCT03077698.

About Endometrial Cancer

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. XBIO-101 may improve sensitivity to progestin therapy in subjects with advanced or recurrent PrR tumors.

About XBIO-101

XBIO-101 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.

Xenetic has commenced patient enrollment in the Phase 2 clinical study of XBIO-101 in conjunction with progestin therapy for the treatment of progestin resistant endometrial cancer, and has filed a protocol under its existing Investigational New Drug application ("IND") to expand the development of XBIO-101 into a biomarker study for the treatment of triple negative breast cancer ("TNBC").

About Xenetic Biosciences

Xenetic Biosciences, Inc. is a clinical-stage biopharmaceutical company focused on the discovery, research and development of next-generation biologic drugs and novel orphan oncology therapeutics. Xenetic's proprietary drug development platforms include PolyXen™, which enables next-generation biologic drugs by improving their half-life and other pharmacological properties. Xenetic's lead investigational product candidates include oncology therapeutic XBIO-101 (sodium cridanimod) for the treatment of progesterone resistant endometrial cancer ("EC"), and a polysialylated form of erythropoietin for the treatment of anemia in pre-dialysis patients with chronic kidney disease.

Xenetic is party to an agreement with Baxalta US Inc. and Baxalta AB (wholly owned subsidiaries of Shire plc) covering the development of a novel series of polysialylated blood coagulation factors. 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 a

significant stockholder of the Company, having invested \$10 million in 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 and additional royalties on sales. The first program under this agreement was a next generation Factor VIII, and this program was terminated by Shire following a Phase 1/2 trial. Xenetic and Shire are currently exploring whether to engage in further development of other blood coagulation factors. Additionally, Xenetic has previously received strategic investments from OPKO Health (Nasdaq: OPK), Serum Institute of India Limited and Pharmasynthez.

Xenetic is also 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 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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