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Xenetic Biosciences Reports Positive Topline Data from Third Cohort of Phase 2 Dose-Escalation Trial of ErepoXen® for Anemia

– Hemoglobin Levels Showed Increase Over Cohort 2 and Maintained Therapeutic Range –

– ErepoXen Generally Well Tolerated with No Antigenic Response –

– Study PK Results Confirm Serum Half Life –

LEXINGTON, Mass.--(BUSINESS WIRE)-- Xenetic Biosciences, Inc. (OTCQB:XBIO) ("Xenetic" or the "Company"), a biopharmaceutical company developing next-generation biologic drugs and novel orphan oncology therapeutics, today announced positive topline data from the third cohort of its Phase 2 dose-escalation study with its lead drug candidate ErepoXen® for the treatment of anemia in pre-dialysis chronic kidney disease patients. This trial is being conducted for Xenetic by Novotech (Australia) Pty Ltd.

The third cohort of the Phase 2, open label, sequential dose finding study to evaluate the safety, pharmacodynamics (PD) and pharmacokinetics (PK) of multiple doses of ErepoXen was launched in October 2015 and was conducted in Australia and South Africa. As in the previous cohorts, patients in the third cohort of this study received injections of ErepoXen every two weeks until hemoglobin levels reached therapeutic levels. The patients then received injections of ErepoXen every 4 weeks (extended dosing interval) during maintenance for a total trial time of 17 weeks.

Professor Simon D Roger M.D., FRACP, Director of Renal Medicine, Gosford Hospital, Australia and Principal Investigator of the study, said, "The results achieved with ErepoXen® in these individuals with chronic kidney disease expand on the initial two cohorts, and, continue to demonstrate a reassuring safety profile. I am very pleased about the potential for ErepoXen® to act as a therapeutic agent to treat these anemic patients and look forward to the continued study of this compound to achieve further results."

The data from the second cohort show that 11 of 12 (91%) of the enrolled patients had an increase in hemoglobin levels over time, and that in 9 of 12 (75%) of the enrolled patients, hemoglobin levels rose into the targeted therapeutic range (10-12 g/dL). The third cohort was designed to achieve a faster rate of rise of hemoglobin than the previous cohorts, but still less than the recommended 1g/dL per 4 weeks.

Data from the third cohort showed that 11 of 14 (79%) of the enrolled patients had an increase in hemoglobin levels over time, and that 10 of 14 (71%) of the enrolled patients,

hemoglobin levels rose into the therapeutic range of 10-12 g/dL. The cohort average hemoglobin level reached the therapeutic range between weeks 4 and 6 after initiation of therapy. Hemoglobin levels were then maintained within the therapeutic range for the remainder of the 17-week study. This compares favorably with the first two cohorts, which showed an increase in the average hemoglobin levels over the course of the 17-week study. In all three cohorts, ErepoXen® was generally well tolerated and there was only one possibly related significant adverse event in cohort 3. In none of the cohorts has there been an increase the immune response as measured by IgG or IgM antibodies to PSA, EPO or PSA-EPO. Overall the safety profile of ErepoXen to maintain red blood cell production and prevent anemia remains favorable. Initial PK results confirmed the original product serum half-life of greater than 400 hours.

“The completion of this third cohort study is a noteworthy step in the development pathway of ErepoXen. We continue to see exciting data being generated and believe ErepoXen has potential to be a promising treatment option for anemic patients,” stated Scott Maguire, CEO. “While the data from this study are positive and maintained the safety profile, we believe that we have not yet reached the most effective clinical dose for these patients. We are therefore continuing this Phase 2 study and look forward to sustained good news. More broadly speaking, the results we are announcing today have increased our confidence in the potential of our patented PolyXen® technology which has significantly changed the biological half-life of epoetin (an injectable form of endogenous erythropoietin) while maintaining its pharmacological activity in humans. We expect that this technology may be applicable to a large variety of therapeutic compounds, not only modifying their biological properties, but also generating new patent exclusivities.”

About ErepoXen®

ErepoXen® is a polysialylated form of recombinant human erythropoietin (EPO), a hormone produced by the kidneys to maintain red blood cell production and prevent anemia. Chronic renal failure or chemotherapy can cause anemia. ErepoXen is under investigation to reduce the required frequency of dosage and side effects and to be less immunogenic than existing treatments. Clinical results of ErepoXen suggest that the drug candidate can be administered once a month. ErepoXen is currently in Phase 2/3 clinical development in collaboration with the Serum Institute of India and SynBio of Russia.

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®, 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™, 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® and Oncohist™ 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 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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