

July 14, 2015



# **Xenetic Biosciences Reports Phase 2 Data on Drug Candidate ErepoXen(R) for Anemia**

***Hemoglobin Levels Rose and were Maintained in Therapeutic Range***

***ErepoXen was Generally Well Tolerated With No Significant Treatment-related Adverse Events***

***Compound uses Patented PolyXen® Technology for Recombinant Erythropoietin***

LEXINGTON, Mass., July 14, 2015 (GLOBE NEWSWIRE) -- **Xenetic Biosciences, Inc.** (OTCQB:XBIO), a biopharmaceutical company focused on developing next-generation biologic drugs and novel oncology therapeutics, announces that it has completed treatment of the second 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. The 12 patients enrolled in this cohort received a biweekly injection of ErepoXen® until hemoglobin levels reached the therapeutic range. The patients then received injections of ErepoXen® every 4 weeks (extended dosing interval) during maintenance for a total trial time of 17 weeks.

The data show 91% of the enrolled patients had an increase in hemoglobin levels over time, and that in 75% of the enrolled patients, hemoglobin levels rose over time 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 cohort of 12 patients, which showed an increase in the average hemoglobin levels over the course of the 17-week study but did not significantly penetrate the desired hemoglobin therapeutic range. In both cohorts, ErepoXen® was generally well tolerated and there were no treatment related significant adverse events. The study was conducted at 10 treatment sites, including eight in Australia and two in New Zealand. A third cohort has been planned to study the effects of an increased dose of ErepoXen® with the objective of ascertaining the optimal therapeutic dose level.

Professor Simon D Roger M.D., FRACP, Director of Renal Medicine, Gosford Hospital, New South Wales, Australia and principal investigator of the study, said, "The results achieved with ErepoXen® in these chronic kidney disease patients are encouraging and should lead to continued study of this compound. We have finished the process of preparing for the third cohort and determining the dose and interval for administration to be studied in this group. We are very encouraged about the potential for ErepoXen® to treat these patients and look forward to providing additional data on the third cohort in 2015."

“Our lead investigational drug candidate, ErepoXen®, continues to generate exciting data as a potential new treatment option for anemia patients, a global market that exceeds \$7 billion annually” said M. Scott Maguire, Chief Executive Officer of Xenetic. “In addition, these results increase our confidence in the potential of Xenetic’s PolyXen® technology to create new, next generation therapeutics from existing, approved therapeutics. In the present case, the use of Xenetic’s patented technology has significantly changed the biological half-life of 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 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 designed and is being studied 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, Russia.

### **About Xenetic Biosciences**

Xenetic Biosciences 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, and OncoHist® for the development of novel oncology drugs focused on orphan indications.

Xenetic's lead product candidates include ErepoXen®, a polysialylated form of erythropoietin (EPO) for the treatment of anemia in pre-dialysis patients with chronic kidney disease, and OncoHist®, a novel recombinant human histone H1.3 molecule for the treatment of refractory Acute Myeloid Leukemia (AML) with potential to treat numerous other cancer indications. Xenetic is collaborating with Russian-based OJSC Pharmsynthez (who is an affiliate of a significant shareholder in Xenetic) and the Serum Institute of India to test additional drug and vaccine candidates and to de-risk the development process with clinical data generated in Russia and India before Xenetic takes these candidates into the clinic in the Western markets.

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](http://www.xeneticbio.com).

### **Baxter Healthcare:**

Xenetic is working together with Baxter International Inc. to develop a novel series of polysialylated blood coagulation factors, including a next generation Factor VIII. This collaboration relies on the PolyXen technology to conjugate PSA to therapeutic blood-clotting factors, with the goal of improving the pharmacokinetic profile and extending the active life of these biologic molecules. Baxter is one of the Company’s largest shareholders having invested in a number of rounds with the most recent investment of \$10M last year.

The agreement is exclusive research, development and license agreement grants Baxter a worldwide, exclusive, royalty-bearing license to Xenetic's PSA patented and proprietary technology in combination with Baxter's proprietary molecules designed for the treatment of blood and bleeding disorders. Under the agreement, Xenetic may receive regulatory and sales target receipts for total potential milestones of up to \$100 million plus royalties on sales.

## Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including but not limited to, the potential safety, tolerability and efficacy of our product candidates and the advancement of our clinical trials. Forward-looking statements can be identified by terminology such as "anticipate," "believe," "could," "could increase the likelihood," "estimate," "expect," "intend," "is planned," "may," "should," "will," "will enable," "would be expected," "designed to," "look forward," "may provide," "would" or similar terms, variations of such terms or the negative of those terms. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the risk of cessation or delay of any of the ongoing or planned clinical trials and/or our development of our product candidates, the risk that the results of previously conducted studies involving similar product candidates will not be repeated or observed in ongoing or future studies involving current product candidates, the risk that our collaboration with Baxter will not continue or will not be successful, and the risk that any one or more of our product candidates will not be successfully developed and commercialized. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our Annual Report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Xenetic undertakes no duty to update this information unless required by law.

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Source: Xenetic Biosciences, Inc.