

# Xenetic Biosciences Partner Completes Dosing of Second Cohort in Phase 2a Study of ErepoXen® in Patients with Chronic Kidney Disease on Dialysis

No serious adverse events seen; dosing of third cohort underway with Xenetic Biosciences' proprietary PolyXen® technology for a "bio-better" erythropoietin

LEXINGTON, Mass.-- **Xenetic Biosciences, Inc. (OTCBB:XBIO**), a biopharmaceutical company focused on developing next-generation biologic drugs and novel oncology therapeutics, announces that its license partner and shareholder Serum Institute of India Limited (SIIL) has completed dosing the 10 patients comprising the second cohort of its Phase 2a study with ErepoXen®, a polysialylated form of erythropoietin (EPO).

A total of 20 patients have been dosed to date in this open-label, single escalating dose study underway in India to assess the efficacy, safety and tolerance of ErepoXen in patients with chronic kidney disease who are on dialysis. The third, and a possible fourth cohort, will enroll a further 10 patients each. Follow-up of all patients and data analysis is expected to be completed no later than the end of the third quarter of 2015.

The first cohort of 10 patients received a one-time intravenous dose of 0.5 ug/kg of ErepoXen. This dose was considered to be well tolerated with no drug-related serious adverse events. No clinically relevant or significant abnormalities or trends were observed. The second cohort of 10 patients received a one-time intravenous dose of 1.5 ug/kg of ErepoXen, and these patients too have not exhibited any serious adverse events. Eight of these patients have completed their 28-day follow up. Results from the second cohort are expected to be reported in the first quarter of 2015. Patient enrollment for the third cohort has started. Dependent upon the results from the third cohort, a fourth cohort may or may not have to be enrolled at a higher dose level.

"With this trial for patients on dialysis, ErepoXen is now in clinical trials for a majority of the anemia indications, which have a global market valued in excess of \$7B. Relative to other marketed EPOs, our 'bio-better' EPO aims to provide a well-tolerated and effective longer-acting therapy," said M. Scott Maguire, chief executive officer of Xenetic Biosciences. "As the Company generates additional clinical data, we will seek a license partner to take this drug forward in the U.S. and Europe. Clinical data to date has been very encouraging and we look forward to reporting more data this year from our Phase 2a company-sponsored studies in Australia and New Zealand – data which will be submitted to the U.S. Food and Drug Administration. We also expect to report on Phase 2b/3 clinical data from the trials being conducted Russia. We are pleased with the progress our partner Serum Institute of India has been making with its own trials, and the data generated by it in this indication will

be very helpful in our own commercialization strategy, as well as providing the potential source of royalty revenues. We look forward to receiving final data from SIIL in 2015."

## About ErepoXen

**ErepoXen**<sup>®</sup> is a polysialylated form of 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 a polysialylated form of EPO designed to reduce the required frequency of dosage, 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® for creating 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®, an improved, polysialylated form of erythropoietin (EPO) for the treatment of anemia in predialysis patients with chronic kidney disease, and OncoHist®, a recombinant human histone H1.3 molecule which Xenetic is developing for the treatment of refractory acute myeloid leukemia (AML). Xenetic is developing a novel series of polysialylated blood coagulation factors through its license agreement with Baxter International Inc. 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 www.xeneticbio.com.

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