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Xenetic Biosciences Announces Dosing of First Patient on Dialysis in Phase 2a Clinical Study of ErepoXen(R)

LEXINGTON, Mass., June 11, 2014 (GLOBE NEWSWIRE) -- Xenetic Biosciences, Inc. (OTCBB:XBIO), a biopharmaceutical company focused on developing next-generation biologic drugs and novel oncology therapeutics, announced today that its partner, the Serum Institute of India, has dosed the first patient in the second cohort of a Phase 2a clinical, sequential single dose study of intravenously (IV) administered ErepoXen® (PSA EPO) for the treatment of anemia in Chronic Kidney Disease (CKD) patients on dialysis.

"We are very pleased to continue progressing the development of ErepoXen®, our most advanced product candidate," said Scott Maguire, Chief Executive Officer of Xenetic. "This Serum Institute-run trial represents our third study of the compound, and joins other trials currently underway in Australia, New Zealand and Russia, where we are holding ICH Compliant and Russian studies of the compound, respectively. We are pleased with the success of our earlier Phase 2 subcutaneous PSA-EPO trials in India, and look forward to working with our international partners to continue developing ErepoXen® as a potential treatment option for anemic patients in need of more effective therapies. With this IV trial, we now cover the two forms of administration for EPO in renal compromised patients, a global market worth over $7 billion. "

ErepoXen® is an improved, polysialylated form of erythropoietin (EPO), a hormone produced by the kidneys to maintain red blood cell production and prevent anemia. ErepoXen® is designed to reduce the required frequency of dosage and side effects, and to be less immunogenic than existing treatments.

In the second cohort of the Phase 2a trial, patients will start with a single ErepoXen® dose of 1.5 mcg/kg body weight. The patient's pharmacodynamic, pharmacokinetic and immunogenic parameters are then followed for the next 28 days. Dose levels in escalating form will then be administered. Safety and experimental parameters will be examined at the end of each dosing cohort before moving onto the next level. The first cohort of patients at the lowest dose level has been finished. The total cost of this India-based trial is being borne by the Serum Institute.

This open-label intravenous trial follows the successful completion of two subcutaneous ErepoXen® clinical trials in India, and is designed to determine the maximum tolerated single dose of ErepoXen®. The first was a Phase 1 single dose range finding study for subcutaneously administered PSA-EPO in healthy volunteers. The second was a Phase 2 single dose range finding study for subcutaneously administered PSA-EPO in CKD patients not on dialysis. There have been no serious adverse events attributable to PSA-EPO reported thus far in over 130 subjects dosed to date.

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 pre-dialysis 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 the company's website at www.xeneticbio.com.

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," "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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