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Xenetic Biosciences Announces Ongoing Safety Data From Phase 2 Trial of ErepoXen(R)

LEXINGTON, Mass., June 30, 2014 (GLOBE NEWSWIRE) -- Xenetic Biosciences, Inc. (OTCBB:XBIO), a biopharmaceutical company focused on developing next-generation biologic drugs and novel oncology therapeutics, today announced results from its ongoing data analysis of the first cohort of its Phase 2, sequential multiple dose study evaluating the safety and efficacy of ErepoXen[®], subcutaneously administered polysialylated erythropoietin (PSA-EPO), for the treatment of anemia in Chronic Kidney Disease (CKD) patients who are neither on dialysis nor receiving erythropoiesis stimulating agents. ErepoXen[®] was found safe and well tolerated to date, with no serious adverse events. This is the first data on repeat dosing of PSA-EPO in human subjects demonstrating its tolerability and safety in Western clinical trials. On this basis, the Safety Review Committee authorized a dose increase for the second cohort of the study, which is currently underway and demonstrating early signs of clinical efficacy. The Safety Review Committee intends to meet again in August 2014, and the Company expects additional results to be available in the third quarter of 2014.

"We are very pleased to announce these safety and tolerability data for ErepoXen[®], our most advanced product candidate," said Scott Maguire, Chief Executive Officer of Xenetic. "This trial represents one of many currently on-going studies of the compound, and supports our continued testing of ErepoXen[®] as a potential treatment option for anemic patients in need of more effective therapies. We expect to seek a commercial partner to assist us in bringing this large market drug candidate through late stage clinical development and potential market launch."

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.

This open-label, sequential multiple dose finding study is designed to determine the dose of ErepoXen[®] that is safe and moves the patient's hemoglobin level into the 10-12 g/dL range. No serious adverse events were reported in the 15 patients evaluated. Gastrointestinal disorders and infections of mild to moderate intensity were reported by 13 patients. None of the events were assessed as being related to the study drug. In addition there is no indication of antibody formation against polysialic acid (PSA), EPO or PSA-EPO in any of the subjects tested 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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