

# Xenetic Biosciences Commences Third Cohort of Phase 2 Trials on Drug Candidate ErepoXen(R) for Anemia

## Trial expands into South Africa

# Compound uses Patented PolyXen® Technology for Recombinant Erythropoietin

LEXINGTON, Mass., Sept. 16, 2015 (GLOBE NEWSWIRE) -- Xenetic Biosciences, Inc. (OTCQB:XBIO), a biopharmaceutical company focused on developing next-generation biologic drugs and novel oncology therapeutics, announced today that it has commenced 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. In an effort to accelerate the recruitment rate, Xenetic has expanded the clinical research sites beyond Australia to now include locations in South Africa. Subjects from this third cohort study will receive injections of ErepoXen® every two weeks until hemoglobin levels reach therapeutic levels. The patients will then receive injections of ErepoXen® every 4 weeks (extended dosing interval) during maintenance for a total trial time of 17 weeks.

The data from the second cohort showed that 91% of the enrolled patients had an increase in hemoglobin levels over time, and that in 75% of the enrolled patients, hemoglobin levels rose into the therapeutic range. The third cohort is designed to further increase the patient's hemoglobin levels into mid-therapeutic range. The study is being performed at nine clinical sites in Australia and six new clinical sites in South Africa. Patient treatment has commenced in Australia. National and local regulatory approvals have been granted in South Africa and patient treatment is expected to start in September. This cohort is expected to be completed in Q2, 2016.

"We expect Cohort three to be the final leg of this phase II trial," said M. Scott Maguire, Chief Executive Officer of Xenetic. "We are excited to share this update with shareholders as the Company progresses along the developmental pathway of our ErepoXen<sup>®</sup> drug candidate.

# About ErepoXen®

ErepoXen<sup>®</sup> 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 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 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 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 <a href="https://www.xeneticbio.com">www.xeneticbio.com</a>.

### Baxalta Incorporated:

Xenetic is working together with Baxalta 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. Baxalta is one of the Company's largest shareholders having invested in a number of previous financing rounds, the most recent being an equity investment of \$10M completed in 2014. The agreement is an exclusive research, development and license agreement which grants Baxalta a worldwide, exclusive, royalty-bearing license to Xenetic's PSA patented and proprietary technology in combination with Baxalta'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 Baxalta 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.

### Contact:

Xenetic Biosciences Inc.
www.xeneticbio.com
M. Scott Maguire, Chief Executive Officer
781 778 7720
j.mccusker@xeneticbio.com

UK/European contact:

Arlington Group Asset Management Limited Ross Ainger +44 (0)207 389 5012 rainger@agam.co.uk

Brokers and Analysts:

Chesapeake Group +1-410-825-3930 info@chesapeakegp.com



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