December 9, 2020

# Xenetic Biosciences, Inc. Announces Positive Data from Partner's Pivotal Phase 3 Clinical Trial Utilizing PolyXen(R) Platform Technology

- ***Xenetic leverages its proprietary drug delivery platform, PolyXen, through partnerships with biotechnology and pharmaceutical companies to improve the half-life and other pharmacological properties of next-generation biologic drugs***
- ***Epolong, a polysialylated form of recombinant human erythropoietin that leverages PolyXen, has been shown to be effective and generally well tolerated in Pharmsynthez-conducted trial as a treatment for anemia in patients with chronic kidney disease***

**FRAMINGHAM, MA / ACCESSWIRE /December 9, 2020 /** Xenetic Biosciences, Inc. (NASDAQ:XBIO) ("Xenetic" or the "Company"), a biopharmaceutical company focused on advancing XCART™, a personalized CAR T platform technology engineered to target patient- and tumor-specific neoantigens, today announced its partner, PJSC Pharmsynthez, has reported in a press release positive data from its pivotal Phase 3 clinical study leveraging PolyXen® to develop a treatment for anemia in patients with chronic kidney disease (CKD).

PolyXen is Xenetic's patent-protected platform technology designed for protein or peptide therapeutics, enabling next-generation biological drugs by prolonging a drug's circulating half-life and potentially improving other pharmacological properties. The PolyXen technology platform was used by Pharmsynthez to develop Epolong (also known as ErepoXen™ or PSA-EPO), a polysialylated form of recombinant human erythropoietin, a hormone produced by the kidneys to promote blood cell production. Pharmsynthez reported in its press release that Epolong is under investigation with the goal of reducing the required dosing frequency and reducing potential side effects, as compared to existing EPO products.

As reported in the press release issued by Pharmsynthez, the pivotal Phase 3 multi-center randomized study was conducted in Russia by Pharmsynthez and was designed to study the efficacy, safety and tolerability of Epolong in comparison with Aranesp® (darbepoetin alfa), the current leader in the long-acting erythropoietin segment. The study enrolled approximately 150 patients with CKD across 36 medical institutions. The results of the study indicated that Epolong was non-inferior to Aranesp with respect to primary and secondary endpoints. Furthermore, the proportion of patients who achieved the target hemoglobin range (10.0-12.0 g/dL inclusive) during the evaluation period was 74% in the Epolong group versus 52% in the Aranesp group. Pharmsynthez also reported that the study revealed that the proportion of patients who exceeded the target threshold level of hemoglobin (12.0 g/dL) was 3.5 times greater in the Aranesp group than in the Epolong group (34.7% versus 10.0%,

respectively).

"The PolyXen platform continues to demonstrate broad utility and ability to modulate the pharmacokinetic and pharmacodynamic profiles of protein drugs. We are pleased with the positive results Pharmsynthez has reported and we look forward to the outcome of their registration filing in Russia for Epolong, which they expect to submit in 2021," commented Jeffrey Eisenberg, Chief Executive Officer of Xenetic.

In clinical and preclinical settings, therapeutic proteins polysialylated with the PolyXen platform have been shown to have extended circulating half-life, improved thermodynamic stability and resistance to proteases, while retaining pharmacological activity. PolyXen has been demonstrated in human clinical trials to confer prolonged half-life on biotherapeutics such as recombinant human erythropoietin and recombinant Factor VIII ("rFVIII"). PolyXen has potential utility in other molecule classes such as peptides and small molecules. The Company is leveraging its PolyXen technology through an exclusive license agreement with Takeda Pharmaceuticals Co. Ltd. in the field of coagulation disorders and receives royalty payments under this agreement.

**About Pharmsynthez**
Pharmsynthez PJSC (MOEX: LIFE) is a Russian pharmaceutical company that develops new medicines, drug technologies for organ-specific delivery, and innovative methods of manufacturing pharmaceutical ingredients. The company is engaged in production and sale of both medicines for the treatment of respiratory diseases (original OM) and active pharmaceutical ingredients (API). The company has a research and production complex in Kapitolovo, commissioned in 2001. Pharmsynthez actively cooperates with North American, Canadian and European companies in the field of chemical compounds and API production.

**About Xenetic Biosciences**
Xenetic Biosciences, Inc. is a biopharmaceutical company focused on progressing XCART™, a personalized CAR T platform technology engineered to target patient- and tumor-specific neoantigens. The Company is initially advancing cell-based therapeutics targeting the unique B-cell receptor on the surface of an individual patient's malignant tumor cells for the treatment of B-cell lymphomas. XCART™ has the potential to fuel a robust pipeline of therapeutic assets targeting high-value oncology indications.

Additionally, Xenetic is leveraging PolyXen®, its proprietary drug delivery platform, by partnering with biotechnology and pharmaceutical companies. PolyXen® has demonstrated its ability to improve the half-life and other pharmacological properties of next-generation biologic drugs. The Company has an exclusive license agreement with Takeda Pharmaceuticals Co. Ltd. in the field of coagulation disorders and receives royalty payments under this agreement.

For more information, please visit the Company's website atwww.xeneticbio.com and connect on Twitter, LinkedIn, and Facebook.

**Forward-Looking Statements**
This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release other than statements of historical facts may constitute forward-looking statements within the meaning of the federal securities laws. These statements can be

identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including, but not limited to, statements regarding: expectations regarding Epolong's investigation and goal of reducing the required dosing frequency and reducing potential side effects compared to existing EPO products; our belief that the PolyXen platform continues to demonstrate broad utility and ability to modulate the pharmacokinetic and pharmacodynamic profiles of protein drugs; expectations regarding the outcome of Pharmsynthez's registration filing in Russia for Epolong and timing of such registration filing, which is expected to be submitted in 2021; our plans to initially apply the XCART technology to advance cell-based therapeutics by targeting the unique B-cell receptor on the surface of an individual patient's malignant tumor cells for the treatment of B-cell lymphomas; our expectations that XCART has the potential to fuel a robust pipeline of therapeutic assets targeting high-value oncology indications; our plans to leverage PolyXen® by partnering with biotechnology and pharmaceutical companies; and our expectation regarding receipt of royalty payments under the exclusive license agreement with Takeda Pharmaceuticals Co. Ltd. Any forward-looking statements contained herein are based on current expectations, and are subject to a number of risks and uncertainties. Many factors could cause our actual activities, performance, achievements, or results to differ materially from the activities and results anticipated in forward-looking statements. Important factors that could cause actual activities, performance, achievements, or results to differ materially from such plans, estimates or expectations include, among others, (1) unexpected costs, charges or expenses resulting from the acquisition of XCART; (2) uncertainty of the expected financial performance of the Company following completion of the acquisition of XCART; (3) failure to realize the anticipated potential of the XCART or PolyXen technology; (4) the ability of the Company to implement its business strategy; (5) failure of the Pharmsynthez to timely register Epolong in Russia, or at all; and (6) other risk factors as detailed from time to time in the Company's reports filed with the SEC, including its annual report on Form 10-K, periodic quarterly reports on Form 10-Q, periodic current reports on Form 8-K and other documents filed with the SEC. The foregoing list of important factors is not exclusive. In addition, forward-looking statements may also be adversely affected by general market factors, general economic and business conditions, including potential adverse effects of public health issues, such as the COVID-19 outbreak on economic activity, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new product candidates and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and the Company does not undertake any obligation to update forward-looking statements, except as required by law.

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**SOURCE:** Xenetic Biosciences, Inc.

https://www.accesswire.com/620082/Xenetic-Biosciences-Inc-Announces-Positive-Data-from-Partners-Pivotal-Phase-3-Clinical-Trial-Utilizing-PolyXenR-Platform-Technology