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Xenetic Biosciences, Inc. Announces Partner's Filing of Registration Dossier in Russia for Epolong Product Candidate That Utilizes Xenetic's PolyXen(R) Platform Technology

- *PJSC Pharmsynthez is leveraging Xenetic's PolyXen® technology to improve the pharmacological properties of its Epolong product candidate pursuant to a royalty-bearing collaboration agreement*
- *Russian registration filing of Epolong, a polysialylated form of recombinant human erythropoietin, follows previously reported positive Phase 3 data for the treatment of anemia in patients with chronic kidney disease*

FRAMINGHAM, MA / ACCESSWIRE / February 16, 2021 / [Xenetic Biosciences, Inc.](https://www.xeneticbiosciences.com) (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 ("Pharmsynthez"), has reported in a press release that it has started the registration phase of Epolong (erythropoietin and polysialic acid conjugate) by filing a registration dossier to obtain approval of Epolong in Russia for the treatment of anemia in patients with chronic kidney disease. The registration dossier is based on previously reported data from Pharmsynthez's Phase 3 clinical trials of Epolong in Russia, which reportedly demonstrated the efficacy of Epolong and its potential to reduce side effects. Pharmsynthez is leveraging Xenetic's PolyXen® technology to improve the pharmacological properties of its Epolong product candidate pursuant to a royalty-bearing collaboration agreement between the Company's wholly-owned subsidiary, Lipoxen Technologies Limited, and Pharmsynthez's wholly-owned subsidiary, SynBio LLC.

"The registration filing in Russia for Epolong represents an important advancement for Pharmsynthez and the Epolong program. If accepted and approved in Russia, Epolong would be the first approved product incorporating our propriety PolyXen delivery platform technology," commented [Jeffrey Eisenberg, Chief Executive Officer](#) of Xenetic.

Pharmsynthez reported in its press release that it expects that the Russian stage of registration activities will be completed in 2021 and that it will be able to start production of Epolong as early as Q1 2022.

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 (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 medicines for the treatment of respiratory diseases (original OM) as well as 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 at www.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 the outcome of Pharmsynthez's registration filing in Russia for Epolong, including that the Russian stage of registration activities will be completed in 2021 and that Pharmsynthez will be able to start production of Epolong as early as Q1 2022; 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 Pharmsynthez to receive approval for its registration for Epolong in Russia or, if approved, to successfully commercialize and market Epolong; 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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