

March 29, 2021



# Xenetic Biosciences, Inc. Receives Approval to Commence Exploratory Study of XCART(TM)

***- Data from the study to provide valuable insights as the Company advances XCART lead program in Non-Hodgkin lymphoma (NHL) towards Investigational New Drug (IND) filing in the United States***

***- Study will evaluate the XCART process of neoantigen identification and generation of tumor-specific CAR T candidates, in a real-world clinical setting***

**FRAMINGHAM, MA / ACCESSWIRE /March 29, 2021 / [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 it has received approval to commence its exploratory patient biopsy study in Eastern Europe evaluating [XCART](#).

"The start of this study represents an important step forward in our preclinical development program, and we look forward to evaluating the XCART platform applied to tumor samples from NHL patients currently under evaluation or in treatment at the study site. Access to biopsy and blood samples from patients with various subtypes and stages of disease will allow us to refine the XCART upstream workflow for isolating and screening tumor-specific neoantigens in order to identify and characterize potential tumor-specific CAR constructs. Importantly, the format of this study will also allow us to evaluate certain clinical parameters relevant to potential Phase 1 studies in the future that would involve dosing of patients with XCART-designed autologous CAR T products. We expect the data generated under this exploratory study to position the Company to conduct U.S. IND-enabling studies," stated [Curtis Lockshin, Ph.D., Chief Scientific Officer](#) of Xenetic.

The exploratory study will be conducted at the Vitebsk Regional Clinical Oncological Center in Minsk, Belarus, and will enroll adult B-Cell NHL patients. When sufficient experience is gained through this exploratory study, the collaborations being leveraged in the XCART development program may be expanded to include development and qualification of manufacturing processes for producing autologous XCART T-Cells. The work being performed under these collaborations is expected to position the Company to conduct IND-enabling studies in the United States.

Xenetic is leveraging academic collaborations with [Scripps Research](#) and [PJSC Pharmsynthez](#) to advance the development of the XCART technology for B-Cell malignancies. Both Scripps Research as well as Pharmsynthez and its collaborators have extensive experience with XCART, having co-invented the technology, and have integral roles in the Company's preclinical development activities.

## 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](http://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: our progress, and expectations regarding timing of, advancing XCART through the preclinical development phase towards a Phase 1 study; our expectations regarding an exploratory biopsy study in Eastern Europe, including those regarding the timing of the commencement of the study, expectations that data from the study will provide valuable insights and that such study will evaluate the XCART process of neoantigen identification and generation of tumor-specific CAR T candidates, in a real-world clinical setting, and the anticipated location and function of the study to be located in Minsk, Belarus to study B-Cell NHL patients; 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 expectations that access to biopsy and blood samples from patients with various subtypes and stages of disease will allow us to refine the XCART upstream workflow for isolating and screening tumor-specific neoantigens, in order to identify and characterize potential tumor-specific CAR constructs; our expectations that the format of the exploratory patient biopsy study will allow us to evaluate certain clinical parameters relevant to potential Phase 1 studies in the future that would involve dosing of patients with XCART-designed autologous CAR T products; our expectation that the data generated under the exploratory patient biopsy study will position the Company to conduct IND-enabling studies in the United States; our expectation that following the experience gained through the exploratory patient biopsy study, the collaborations being leveraged in the XCART development program may be expanded to include development and qualification of manufacturing processes for producing autologous XCART T-Cells; 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 Scripps Research and/or Pharmsynthez or the other academic institutions in Eastern Europe, including Belarus and Russia (as applicable) to perform their obligations under the respective agreements; (6) failure of the Company and Pharmsynthez to reach agreements with the contract sites on terms favorable to the Company, or at all; (7) failure of Pharmsynthez to receive approval for its registration for Epolong in Russia or, if approved, to successfully commercialize and market Epolong; and (8) 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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