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Xenetic Biosciences, Inc. Announces Publication of Data from Partner's Phase 1/2 Study Evaluating Program Leveraging Polyxen(R) Platform Technology

- SHP656 program utilized Xenetic's PolyXen platform technology to conjugate polysialic acid to therapeutic blood-clotting factors**
- Phase 1/2 study demonstrated SHP656's efficacy and pharmacokinetic data commensurate with the profile of an extended half-life rFVIII product**

FRAMINGHAM, MA / ACCESSWIRE /January 14, 2020 / [Xenetic Biosciences, Inc.](#) (NASDAQ:XBIO) ("Xenetic" or the "Company"), a biopharmaceutical company focused on advancing XCART™, a personalized chimeric antigen receptor T cell ("CAR T") platform technology engineered to target patient-specific tumor neoantigens, announced today that data from the completed Phase 1/2 clinical study of SHP656 ("PSA-recombinant Factor VIII", "PSA-rFVIII") sponsored by its license partner Takeda Pharmaceuticals Company Limited ("Takeda") has been published in the journal *Haemophilia*¹.

The results from this single-dose study indicate that polysialylation of rFVIII confers a half-life extension similar to that of approved extended half-life products that use either PEG or Fc fusion technology and was not associated with any treatment-emergent adverse events.

The Phase 1/2 clinical study was conducted by Baxalta US Inc, a Takeda company, to evaluate SHP656, which was being developed as a long-acting therapeutic for the treatment of hemophilia A utilizing Xenetic's PolyXen technology to conjugate polysialic acid to therapeutic blood-clotting factors.

[Jeffrey Eisenberg, Chief Executive Officer](#) of Xenetic, commented, "We are pleased that this study published in the peer-reviewed journal *Haemophilia* has demonstrated that our PolyXen platform successfully extended the circulating half-life of rFVIII with no treatment-related adverse events."

Data from SHP656 was also published in the *Journal of Pharmaceutical Sciences*² in an article titled, "Polysialic Acid-Mediated Activity Measurement of Polysialylated Recombinant Coagulation Factor VIII," and in the *Journal of Pharmacology and Experimental Therapeutics*³ in an article titled, "Evaluation of Factor VIII Polysialylation: Identification of a Longer-Acting Experimental Therapy in Mice and Monkeys."

PolyXen is Xenetic's patent-protected platform technology for creating next-generation protein or peptide therapeutics, by prolonging a drug's circulating half-life and potentially improving other pharmacological properties.

With the Phase 1/2 study completed in May 2017, SHP656 is no longer part of an active development program.

Takeda currently has one active development program underway utilizing the PolyXen platform technology, under an Exclusive License Agreement with Xenetic in the field of coagulation disorders. In addition, in October 2017 Xenetic granted rights to Takeda to grant a nonexclusive sublicense to certain patents related to PolyXen to a third party, and Xenetic receives royalties under that arrangement in the near term.

About Xenetic Biosciences

Xenetic Biosciences, Inc. is a biopharmaceutical company focused on progressing XCART, a personalized CAR T platform technology engineered to target patient-specific tumor 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 the Company's 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; the Company's expectations that XCART has the potential to fuel a robust pipeline of therapeutic assets targeting high-value oncology indications; and the Company's expectations regarding potential royalties resulting from the sublicense with Takeda commencing in the near term. 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 or results to differ materially from the activities and results anticipated in forward-looking statements. Important factors that could cause actual results to differ materially from such plans, estimates or expectations include, among others, (1) unexpected costs, charges or expenses resulting from the acquisition of the CAR T technology; (2) uncertainty of the expected financial performance of the Company following completion of the acquisition of the CAR T technology; (3) failure to realize the anticipated

potential of the XCART technology; (4) the ability of the Company to implement its business strategy; and (5) 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, 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.

[1] [Haemophilia. 2019 Nov 28. doi:10.1111/hae.13878](https://doi.org/10.1111/hae.13878)

[2] [J Pharm Sci. 2019 Oct 16. pii : S0022 3549\(19\)30656 2](#)

[3] [J Pharmacol Exp Ther. 2019 Oct;371\(1\):95 105.](#)

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