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# Xenetic Biosciences Receives Program Update from Partner Shire's Phase 1/2 Study Evaluating SHP656 in Development as a Long-acting Treatment for Hemophilia A

*SHP656 program utilizes Xenetic's PolyXen™ platform technology to conjugate polysialic acid to therapeutic blood-clotting factors*

LEXINGTON, Mass.--(BUSINESS WIRE)-- [Xenetic Biosciences, Inc.](#) (NASDAQ:XBIO) ("Xenetic" or the "Company"), a clinical-stage biopharmaceutical company focused on the discovery, research and development of next-generation biologic drugs and novel orphan oncology therapeutics, announced today that it has received an update on the Phase 1/2 clinical study conducted by its partner Shire, evaluating SHP656 ("PSA-recombinant Factor VIII", "PSA-rFVIII"), which is being developed as a long-acting therapeutic for the treatment of hemophilia A utilizing Xenetic's PolyXen™ platform technology to conjugate polysialic acid to therapeutic blood-clotting factors. The Phase 1/2 study demonstrated SHP656's efficacy and pharmacokinetic data commensurate with the profile of an extended half-life rFVIII product. Additionally, there were no drug-related adverse events, serious adverse events, or rFVIII inhibitors reported. However, in this study, a pre-defined once-weekly dosing criterion was not met.

"Despite not achieving the principal objective of once-weekly dosing in this Phase 1/2 study, our PolyXen technology clearly works as a platform to successfully extend the circulating half-life of rFVIII with no drug-related serious adverse events," stated M. Scott Maguire, Xenetic's Chief Executive Officer.

"Including our own studies with a polysialylated erythropoietin ("PSA-EPO", "ErepoXen®") candidate, this is the second instance in which PolyXen has been demonstrated, in a human clinical trial setting, to confer extended half-life to a biotherapeutic, while maintaining pharmacological activity and a favorable safety and tolerability profile. Moving forward, we believe data from Shire's SHP656 program continues to support the broad utility of our proprietary PolyXen technology platform, and we remain focused on building a growing pipeline of partnerships utilizing this proven platform. We truly value our continuing relationship with Shire and look forward to exploring other potential applications of PolyXen within the Shire portfolio," added Mr. Maguire.

"While Shire is disappointed by this outcome, the company is encouraged by the knowledge gained through this research and remains committed to transforming the treatment landscape for patients with bleeding disorders. Given the potential application of polysialic

acid technology, the companies will explore future collaborations,” stated Philip Vickers, Ph.D., Global Head of Research & Development at Shire.

### **About PolyXen™**

PolyXen™ is a patent-protected platform technology for creating proprietary, next-generation protein therapeutics by attaching polysialic acid (“PSA”), a biodegradable polymer found in living systems, to existing protein or peptide therapeutics, which can improve their pharmacological properties.

Attachment of PSA (“polysialylation”) to a therapeutic increases its apparent size, which reduces systemic clearance rates, while shielding the protein from other degradation pathways. The PolyXen platform permits optimization of a target therapeutic’s pharmacological properties, by controlling the amount, size, and sites of attachment of the PSA polymers.

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. Numerous human clinical trials to date have shown no evidence of PSA- induced immunogenicity.

### **About Xenetic Biosciences**

Xenetic Biosciences, Inc. is a clinical-stage biopharmaceutical company focused on the discovery, research and development of next-generation biologic drugs and novel orphan oncology therapeutics. Xenetic's proprietary drug development platforms include PolyXen™, which enables next-generation biologic drugs by improving their half-life and other pharmacological properties. Xenetic's lead investigational product candidates include oncology therapeutic XBIO-101 (sodium cridanomod) for the treatment of progesterone resistant endometrial cancer (EC), and a polysialylated form of erythropoietin for the treatment of anemia in pre-dialysis patients with chronic kidney disease.

Xenetic is party to an agreement with Baxalta US Inc. and Baxalta AB (wholly owned subsidiaries of Shire plc) covering the development of a novel series of polysialylated blood coagulation factors. This collaboration relies on Xenetic's PolyXen technology to conjugate polysialic acid (“PSA”) to therapeutic blood-clotting factors, with the goal of improving the pharmacokinetic profile and extending the active life of these biologic molecules. Shire is a significant stockholder of the Company, having invested \$10 million in the Company during 2014. The agreement is an exclusive research, development and license agreement which grants Shire a worldwide, exclusive, royalty-bearing license to Xenetic's PSA patented and proprietary technology in combination with Shire's proprietary molecules designed for the treatment of blood and bleeding disorders. Under the agreement, Xenetic may receive regulatory and sales target payments for total potential milestone receipts of up to \$100 million and additional royalties on sales. The first program under this agreement was a next generation Factor VIII, and this program was terminated by Shire following a Phase 1/2 trial. Xenetic and Shire are currently exploring whether to engage in further development of other blood coagulation factors. Additionally, Xenetic has previously received strategic investments from OPKO Health (Nasdaq: OPK), Serum Institute of India Limited and PharmSynthez.

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 [www.xeneticbio.com](http://www.xeneticbio.com) and connect on [Twitter](#), [LinkedIn](#), [Facebook](#) and [Google+](#).

### **Forward-Looking Statements**

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding expected benefits of NGS cancer panels, the ability to accurately determine the heritable factors increasing the risk of cancer, permitting tailored treatment, screening and prevention of cancer in patients, as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described in our filings with the Securities and Exchange Commission, as well as the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments. 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 products 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 we do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

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