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Xenetic Biosciences Receives $3 Million Milestone Payment from Shire plc for PSA-Recombinant SHP656 in Development for Long-Acting Treatment for Hemophilia

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 Xenetic received a $3 million milestone payment from Shire plc (LSE: SHP, NASDAQ: SHPG) related to Shire's advancing the Phase 1/2a clinical study for the PSA-Recombinant SHP656 or Factor VIII ("FVIII") being developed as a long-acting therapeutic for the treatment of hemophilia. The stated goal of Shire is to introduce an innovative FVIII protein that can significantly prolong the circulating half-life of the FVIII protein, with the objective of providing a once weekly treatment or reaching higher trough activity levels for greater efficacy.

"We are thrilled with the progress that Shire has made developing the SHP656 program, which is currently in Phase 1/2a clinical trials for the treatment of hemophilia," said Scott Maguire, Xenetic's Chief Executive Officer. "We look forward to the continued development of SHP656 utilizing our proprietary PolyXen™ platform technology with the goal of having a once weekly or less frequent dosing, thereby making it the longest acting hemophilia A factor replacement treatment in development in the $9.3 billion global hemophilia market(1)."

Xenetic announced its exclusive research, development, license and supply agreement with Shire plc (formerly Baxalta, Baxter Incorporated and Baxter Healthcare) in January 2014. The collaboration with Shire utilizes Xenetic's PolyXen platform technology to conjugate polysialic acid ("PSA") to therapeutic blood-clotting factors, with the goal of improving the pharmacokinetic profile and extending the active half-life of these biologic molecules. Shire is running and funding the SHP656 program, which is currently in a Phase 1/2a clinical trial. Shire filed a Clinical Trial Application ("CTA") for the program in Q4 2015 and commenced human clinical trials during the first quarter of 2016.

Under the January 2014 license deal, Xenetic is entitled to up to $100 million in potential development, regulatory, sales and deadline extension receipts, which are contingent on the performance of Shire achieving certain milestones. Xenetic is also entitled to royalties on potential net sales. In connection with this deal, in 2014 Shire made a $10 million equity investment in the Company. Combined with a previous $3 million equity investment, Shire is one of the Company's largest shareholders.

Shire is a leading global biotechnology company focused on serving people affected by rare diseases and highly specialized conditions.

(1) Source: http://www.grandviewresearch.com/industry-analysis/hemophilia-treatment-industry

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 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 FDA orphan designated oncology therapeutic sodium cridanimod for the treatment of progesterone receptor negative endometrial cancer, and a polysialylated form of erythropoietin for the treatment of anemia in pre-dialysis patients with chronic kidney disease.

Xenetic is also working together with Shire plc (formerly Baxalta, Baxter Incorporated and Baxter Healthcare) to develop a novel series of polysialylated blood coagulation factors, including a next generation Factor VIII. 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 one of the Company's largest shareholders having invested $10 million in the common stock of 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 plus royalties on sales.

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 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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Jenene Thomas Communications, LLC.
Jenene Thomas, 908-938-1475
jenene@jenenethomascommunications.com

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