

## Xenetic Biosciences Presents Case Study of PolyXen™ Platform Technology at the 13th Annual Protein Engineering Summit (PEGS) Boston

- Biodegradable, hydrophilic and non-immunogenic polysialic acid for drug delivery utilizes
  PolyXen technology to overcome current limitations with protein therapeutics –
- Case study demonstrates that polysialylated erythropoietin remained structurally intact,
  and physiologically active with an increased half-life in human circulation –
- PolyXen case study presented in a scientific poster presentation on May 1-2, 2017 and an oral presentation on May 2, 2017 at 9:00 AM EDT –

LEXINGTON, Mass.--(BUSINESS WIRE)-- <u>Xenetic Biosciences</u>, <u>Inc.</u> (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 is presenting a case study highlighting the Company's proprietary drug development platform technology, <u>PolyXen™</u>, at the <u>13<sup>th</sup> Annual PEGS Boston</u> conference being held May 1 − 5, 2017 in Boston, MA.

The abstract titled, "Polysialylation – A Platform Technology for Enhancing Therapeutic Proteins and Its Clinical Application," is being presented in a scientific poster presentation as a part of "Poster Session A" on May 1 – 2, 2017. Curtis A. Lockshin, Ph.D., Chief Scientific Officer of Xenetic will also present results from the case study in an oral presentation on Tuesday, May 2, 2017 at 9:00 AM EDT as part of the Conquering Disease session of the Fusion Protein Therapeutics track of the Bioconjugates stream.

PolyXen is Xenetic's platform technology designed to improve the half-life and other pharmacological properties of biologic drugs, in which polysialic acid ("PSA"), a naturally occurring, hydrophilic, non-immunogenic, linear homopolymer of sialic acid (colominic acid), is attached to a protein to improve its *in vivo* pharmacokinetics and pharmacodynamics.

The positive data from the case study showed that the attachment of PSA ("polysialylation") led to retained or only slightly decreased biological activity, improved stability against proteases and thermal stress, and significantly prolonged circulating half-life. For example, the half-life of polysialylated erythropoietin ("PSA-EPO", "ErepoXen $^{TM}$ ") = ~400 hours in patients with chronic kidney disease ("CKD") after subcutaneous administration, versus the half-life of rhEPO = ~22 hours.

The Company's PolyXen delivery technology has been clinically validated in Phase 1 and

Phase 2 studies, where ErepoXen was shown to be efficacious at correcting and maintaining hemoglobin levels, while being well tolerated in humans, and without eliciting immune response after repeated dosing. ErepoXen is currently in ongoing Phase 2/3 clinical development through the Company's partners and shareholders, the Serum Institute of India and SynBio of Russia, for the treatment of anemia in CKD patients.

The Phase 1 and Phase 2 clinical trials of ErepoXen in CKD patients not on dialysis, highlighted its significantly improved pharmacokinetic properties and non-immunogenicity, suggesting that PSA-EPO has commercial potential as a next-generation long-acting ESA for managing anemia. The PolyXen polysialylation platform has been expanded to improve other therapeutic proteins, including PSA-FVIII, which is currently being evaluated in a Phase 1/2 clinical trial for the treatment of hemophilia A with Xenetic's partner, Shire plc (LSE: SHP, NASDAQ: SHPG).

"We continue to establish a growing body of data demonstrating the broad utility of Xenetic's proprietary PolyXen platform technology for the creation of next-generation protein therapeutics, which confers the same benefits without many of the shortcomings which exist in the current therapies," commented Dr. Lockshin. "These significant, pharmacologically important attributes such as biodegradability, protease protection, enhanced thermal stability, immune system shielding and half-life extension make the addition of polysialic acid to therapeutics a clear advantage over other technologies."

The poster being presented at the 13<sup>th</sup> Annual PEGS Boston will be accessible on the <u>Publications</u> page of the Company's website, <u>www.xeneticbio.com</u> following the conference.

## 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 cridanimod) 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 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 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 plus royalties on sales. 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 <a href="https://www.xeneticbio.com">www.xeneticbio.com</a> and connect on <a href="https://www.xeneticbio.com">Twitter, LinkedIn, Facebook</a> and <a href="https://www.xeneticbio.com">Google+</a>.

## **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 statements regarding our potential for future growth and creation of shareholder value, our anticipated corporate development strategies and the advancement of the clinical development of our oncology drug candidates based upon our PolyXen™ platform technology. 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. These risks and uncertainties include those described in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and filed with the Securities and Exchange Commission on March 31, 2017, and subsequent reports that we file with the Securities and Exchange Commission. 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.

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