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Xenetic Biosciences, Inc. Engages Catalent for Clinical Manufacturing to Advance DNase-Based Oncology Platform Towards Phase 1 Study

- *DNase-based oncology platform has the potential to improve outcomes of existing therapeutic agents in multiple solid tumor indications*
- *Systemic DNase program initially targeting multi-billion-dollar indications including pancreatic carcinoma*

FRAMINGHAM, MA / ACCESSWIRE / July 7, 2022 [Xenetic Biosciences, Inc.](#)

(NASDAQ:XBIO) ("Xenetic" or the "Company"), a biopharmaceutical company focused on advancing innovative immune-oncology technologies addressing hard-to-treat cancers, today announced it has entered into a manufacturing agreement with Catalent Pharma Solutions LLC ("Catalent"), which will include cGMP manufacturing for the Company's recombinant protein, Human DNase I.

Catalent is the global leader in enabling biopharma, cell, gene, and consumer health partners to optimize development, launch, and supply of better patient treatments across multiple modalities.

"We are pleased to be working with a preeminent contract development and manufacturing organization such as Catalent, and to have the opportunity to leverage their broad expertise and successful track record with early-stage development through commercial manufacturing. We are excited to take this step forward on the path to the clinic and look forward to investigating systemic DNase as an adjunctive therapy for locally advanced or metastatic cancers," commented, [Jeffrey Eisenberg, Chief Executive Officer](#) of Xenetic.

"This agreement is an important step towards long-term collaboration between Catalent and Xenetic," added Vikalp Mohan, Global Vice President, Head of Drug Substance at Catalent Biologics. "We look forward to leveraging Catalent's proven biomanufacturing expertise at our site in Madison, Wisconsin to support the advancement of Xenetic's DNase clinical development program and accelerating their path to first-in-human studies."

Xenetic's interventional DNase based oncology platform is aimed at improving outcomes of existing treatments, including immunotherapies. The Company exclusively licensed intellectual property for uses of DNases in cancer include systemic co-administration of DNases along with standard therapies, including chemotherapy, radiation and checkpoint inhibitors, or along with conventional chimeric antigen receptor (CAR) T therapies.

The DNase platform is designed to target neutrophil extracellular traps ("NETs"), which are

weblike structures composed of extracellular chromatin coated with histones and other proteins. NETs are expelled by activated neutrophils, in response to microbial or pro-inflammatory challenges. However, excessive production or reduced clearance of NETs can lead to aggravated inflammatory and autoimmune pathologies, as well as creation of pro-tumorigenic niches in the case of cancer growth and metastasis.

The Company is working toward its planned first-in-human study to evaluate DNase combined with immune checkpoint inhibitors or chemotherapy.

About Catalent

Catalent is the global leader in enabling pharma, biotech, and consumer health partners to optimize product development, launch, and full life-cycle supply for patients around the world. With broad and deep scale and expertise in development sciences, delivery technologies, and multi-modality manufacturing, Catalent is the industry's preferred partner for personalized medicines, consumer health brand extensions, and blockbuster drugs. Catalent helps accelerate over 1,000 partner programs and launch over 150 new products every year. Its flexible manufacturing platforms at over 50 global sites supply over 70 billion doses of nearly 7,000 products to over 1,000 customers annually. Catalent's expert workforce exceeds 19,000, including more than 2,500 scientists and technicians. Headquartered in Somerset, New Jersey, the company generated \$4 billion in revenue in its 2021 fiscal year. For more information, visit www.catalent.com.

About Xenetic Biosciences

Xenetic Biosciences, Inc. is a biopharmaceutical company focused on advancing innovative immune-oncology technologies addressing hard to treat oncology indications. The Company's DNase oncology platform, in development for the treatment of solid tumors, is aimed at improving outcomes of existing treatments, including immunotherapies, by targeting neutrophil extracellular traps (NETs). The Company is also developing its personalized CAR T platform technology, XCART™, to develop 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.

Additionally, Xenetic is leveraging PolyXen®, its proprietary drug delivery platform, to partner 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 receives royalty payments under an exclusive license arrangement in the field of blood coagulation disorders.

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 that we intend to be subject to 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: expectations regarding the manufacturing agreement with Catalent and the DNase platform, including our plans to use Catalent for clinical manufacturing to advance the DNase platform towards a Phase 1 study, our belief that the DNase based oncology platform has the potential to improve outcomes of existing therapeutic agents in multiple solid tumor indications, our expectations that the systemic DNase program is initially targeting multi-billion-dollar indications, including pancreatic Carcinoma, our plans to investigate systemic DNase as an adjunctive therapy for locally advanced or metastatic cancers, that the DNase oncology platform is aimed at improving outcomes of existing treatments, including immunotherapies, by targeting NETs, our plans to advance innovative immune-oncology technologies to address hard to treat oncology indications, and our expectations regarding working toward our first-in-human study to evaluate DNase combined with immune checkpoint inhibitors or chemotherapy; plans regarding our personalized CAR T platform technology, XCART™, being used to develop 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; our plans to leverage PolyXen®, our proprietary drug delivery platform, to partner with biotechnology and pharmaceutical companies; and our expectations regarding the receipt of royalty payments under an exclusive license agreement in the field of blood coagulation disorders. 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 manufacturing agreement with Catalent; (2) unexpected costs, charges or expenses resulting from the licensing of the DNase platform; (3) uncertainty of the expected financial performance of the Company following the licensing of the DNase platform; (4) failure to realize the anticipated potential of the DNase, XCART or PolyXen technologies; (5) the ability of the Company to implement its business strategy; and (6) 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, 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, and geopolitical events, such as the Russian invasion of Ukraine, 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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