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Xenetic Biosciences, Inc. Expands Oncology Pipeline with In-Licensing of DNase Based Oncology Platform Comprising Multiple Therapeutic Modalities

Transaction with CLS Therapeutics for DNase platform includes two pre-clinical development programs and creates near-term clinical development opportunity

DNase based oncology platform has the potential to improve outcomes of existing therapeutic agents in multiple solid tumor indications

Xenetic plans to conduct a Phase 1 clinical study of lead asset in locally advanced or metastatic solid tumors

Company to host update conference call and webcast today, April 27th at 8:30 AM ET

FRAMINGHAM, MA / ACCESSWIRE / April 27, 2022 [/Xenetic Biosciences, Inc.](https://www.xeneticbiosciences.com) (NASDAQ:XBIO) ("Xenetic" or the "Company"), a biopharmaceutical company focused on advancing innovative immune-oncology technologies for the treatment of hard to treat cancers, today announced that it has entered into exclusive license and sublicense agreements with CLS Therapeutics ("CLS") to develop its interventional DNase based oncology platform, which is aimed at improving outcomes of existing treatments, including immunotherapies. Xenetic will host a conference call and webcast, today, April 27, 2022, at 8:30 a.m. ET (details below).



Under the terms of the agreements, Xenetic has an exclusive license to CLS' intellectual property, for uses of DNases in cancer, including 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. In addition, the licenses cover "DNase-armored" CAR T therapies in which novel CAR T products are engineered to secrete DNases into the tumor microenvironment to potentially improve T-cell infiltration, activity and persistence. As part of the agreements, Xenetic will make an upfront payment of \$500,000 in cash and issue 875,000 shares of common stock, and will make future payments based on the achievement of certain clinical and regulatory milestones of up to \$13 million per program, as well as issue up to an additional 950,000 shares of

common stock based on the achievement of certain milestones. Additionally, Xenetic will pay tiered royalty payments ranging from mid-single to low-double digits on any potential future sales, as well as a percentage share of certain consideration received by Xenetic from sublicensees.

The licensed 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.

A substantial amount of scientific literature has implicated NETs in the context of cancer pathogenesis and resistance to cancer therapies (including chemo, radio, and immunotherapies such as checkpoint inhibitors and cell therapies). In published reports, elevated levels of NETs have been a biomarker associated with poor prognosis in patients with a variety of cancers.

In addition, resistance to existing therapeutic agents can involve the release of immunosuppressive signaling factors from NETs, or physical barriers created by NETs which can impede the infiltration, activity, and survival of cytotoxic T cells in the tumor microenvironment.

Published pre-clinical models have demonstrated the effectiveness of systemically administered DNase, alone or in combination with other agents, for the elimination of NETs and prevention of tumor growth and metastasis.

"We are excited to in-license this oncology platform. Based on the compelling pre-clinical efficacy data seen to date, we believe the DNase-based oncology platform has the potential to improve the outcomes of chemotherapy and immunotherapy treatments in multiple solid tumor indications," commented Jeffrey Eisenberg, Chief Executive Officer of Xenetic. "This transaction provides Xenetic with near term opportunities for value-driving milestones, and an anticipated timeline to clinic that now positions us as an emerging clinical-stage company. This gives us the confidence to focus our capital and human resources on advancing the DNase pipeline. Our primary efforts are now aimed at advancing the systemic DNase program into the clinic as an adjunctive therapy for locally advanced or metastatic cancers. Our goal is to provide solutions in the treatment of solid tumors by improving response and overcoming resistance to checkpoint inhibitors or chemotherapy. Ultimately, we expect these programs to drive value for shareholders in the near and long term."

Adoptive transfer of CAR T cells has emerged as one of the most promising advances in cancer immunotherapy. Engineered CAR T cells, designed to recognize cancer-associated antigens, are capable of sustained and selective killing of tumor cells, with substantial reduction of tumor burden. CAR T therapies have exhibited remarkable clinical success against hematological malignancies but thus far have failed to demonstrate success in the context of solid tumors. Published evidence suggests that in addition to immunosuppressive factors, mechanical barriers formed by NETs can impede T-cell penetration and occlude T-cell contact with tumor cells.

"To successfully treat solid tumors, CAR T cells must be able to infiltrate, persist, and

maintain anti-tumor function in a hostile tumor microenvironment that is itself adept at immunosuppression and conducive to tumor cell survival. Recent approaches to CAR T design include "armored" CAR-T cells, so named because they can express additional factors to resist immunosuppression or degrade physical components of the tumor's extracellular matrix, including NETs. We intend to conduct pre-clinical research with the goal of demonstrating that armoring CAR T cells to secrete DNase can support depth and durability of response against solid tumor indications," said Curtis Lockshin, Chief Scientific Officer of Xenetic.

Conference Call and Webcast

Xenetic management will host a conference call and webcast presentation for investors, analysts, and other interested parties to discuss the in-licensing today, April 27, 2022, at 8:30 AM ET.

Interested participants and investors may access the conference call by dialing (877) 407-9708 (domestic) or (201) 689-8259 (international). The [live webcast](#) will be accessible on the [Events](#) page of the [Investors](#) section of the Xenetic website, xeneticbio.com, and will be archived for 90 days.

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 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 transaction with CLS Therapeutics, including all statements regarding the DNase platform, such as our expectations regarding the DNase

platform creating near-term clinical development opportunity and our belief that the DNase based oncology platform has the potential to improve outcomes of existing therapeutic agents in multiple solid tumor indications, expectations regarding future cash and equity payments under the licenses based on the achievement of certain clinical and regulatory milestones, expectations regarding payment of royalties or sublicensee income, our plans to conduct a Phase 1 clinical study of lead asset in locally advanced or metastatic solid tumors, our belief that the CLS transaction provides us with near term opportunities for value-driving milestones and an anticipated timeline to clinic that now positions us as an emerging clinical-stage company, our plans to focus our capital and human resources on advancing the DNase pipeline, expectations that our primary efforts are now aimed at advancing the systemic DNase program into the clinic as an adjunctive therapy for locally advanced or metastatic cancers, our expected goal to provide solutions in the treatment of solid tumors by improving response and overcoming resistance to checkpoint inhibitors or chemotherapy, our expectations that these programs will drive value for shareholders in the near and long term, and our intentions to conduct pre-clinical research with the goal of demonstrating that armoring CAR T cells to secrete DNase can support depth and durability of response against solid tumor indications; expectations regarding our focus on advancing innovative immune-oncology technologies addressing hard to treat oncology indications; our plans to develop our 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; and our plans to leverage PolyXen® by partnering with biotechnology and pharmaceutical companies. 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 transaction with CLS Therapeutics and the acquisition of the DNase platform; (2) uncertainty of the expected financial performance of the Company following completion of the transaction with CLS Therapeutics and the acquisition of the DNase platform; (3) failure to realize the anticipated potential of the DNase platform or XCART or PolyXen technologies; (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, general economic and business conditions, including potential adverse effects of public health issues, such as the COVID-19 outbreak 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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