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Qualigen Therapeutics Expands Research Agreement with University of Louisville for ALAN Cancer Drug Candidate

In addition to acute myeloid leukemia, preclinical studies will focus on glioblastoma and lung cancer, and the use of ALAN as a potential adjuvant therapy

CARLSBAD, Calif., Oct. 1, 2020 /PRNewswire/ --**Qualigen Therapeutics, Inc.** (NASDAQ: QLGN) announces it has entered into an amended Sponsored Research Agreement with the University of Louisville (UofL) to advance development of Qualigen's anticancer drug candidate AS1411-GNP, also known as ALAN (Aptamer-Linked Anti-Nucleolin).

The work being performed under the original Sponsored Research Agreement comprises animal studies to assess antitumor efficacy and safety of different ALAN compositions designed to treat pediatric and adult acute myeloid leukemia (AML). Under the amended Sponsored Research Agreement UofL will perform preclinical studies on AML and on additional indications including glioblastoma, a malignant brain cancer that is difficult to treat because most drugs cannot pass the blood-brain membrane, and non-small cell lung cancer, which comprises approximately 85% of the 1.6 million global lung cancer cases each year.

Additionally, Qualigen and UofL will study how ALAN may inhibit metastasis of cancer cells as a potential adjuvant therapy. The recurrence of cancer after initial treatment is the cause of approximately 90% of cancer deaths and represents a pressing unmet clinical need.

"Our expanded agreement with UofL should provide Qualigen with additional data to help us achieve our goal of advancing our ALAN cancer drug candidate into clinical trials against AML next year. We are especially interested in several new applications of this drug candidate, namely the treatment of pediatric cancers such as leukemia, the treatment of glioblastoma, the deadliest form of brain cancer and as an adjuvant therapy to stop the recurrence of cancer after initial treatment. We believe these paths will become a larger part of our clinical efforts and will accelerate the expansion of our product pipeline over the coming year, as they represent high unmet needs for critically important areas of cancer treatment," stated Michael Poirier, President, Chief Executive Officer and Chairman of Qualigen.

ALAN is a combination of AS1411 plus a DNA-coated gold nanoparticle, which dramatically increases its potency. This cancer drug candidate has the potential to target and destroy tumor cells in a wide variety of cancer types with minimal side effects. The Company is aiming to commence Phase 1 human trials in 2021 for AML, its lead indication. Qualigen has an exclusive worldwide license agreement from the UofL for ALAN.

"We are pleased to continue our relationship with Qualigen Therapeutics to expand the development program for ALAN," added Paula Bates, PhD, Professor of Medicine at UofL, who will be leading the project at UofL in collaboration with Martin O'Toole, PhD, and Levi Beverly, PhD. "We look forward to conducting these studies, which have the potential to demonstrate ALAN's broad applicability as an effective therapy for these difficult-to-treat cancers."

About Qualigen Therapeutics, Inc.

Qualigen Therapeutics, Inc. is a biotechnology company focused on developing novel therapeutics for the treatment of cancer and infectious diseases, as well as maintaining and expanding its core FDA-approved FastPack® System, which has been used successfully in diagnostics for almost 20 years. The Company's cancer therapeutics pipeline includes ALAN (AS1411-GNP), RAS-F and STARS™. ALAN (AS1411-GNP) is a DNA coated gold nanoparticle cancer drug candidate that has the potential to target various types of cancer with minimal side effects. The foundational aptamer of ALAN, AS1411, is also being studied for use in treating or even preventing viral-based infectious diseases, including COVID-19. RAS-F is a family of RAS oncogene protein-protein interaction inhibitor small molecules for preventing mutated RAS genes' proteins from binding to their effector proteins; preventing this binding could stop tumor growth, especially in pancreatic, colorectal and lung cancers. STARS is a DNA/RNA-based treatment device candidate for removal from circulating blood of precisely targeted tumor-produced and viral compounds. Because Qualigen's therapeutic candidates are still in the development stage, Qualigen's only products that are currently commercially available are FastPack System diagnostic instruments and test kits, used in physician offices, clinics and small hospitals around the world. The FastPack System menu includes rapid point-of-care diagnostic tests for cancer, men's health, hormone function, vitamin D status and antibodies against SARS-CoV-2. Qualigen's facility in Carlsbad, California is FDA and ISO Certified and its FastPack product line is sold worldwide by its commercial partner Sekisui Diagnostics, LLC. For more information on Qualigen Therapeutics, Inc., please visit https://www.qualigeninc.com/.

Forward-Looking Statements

This news release contains forward-looking statements by the Company that involve risks and uncertainties and reflect the Company's judgment as of the date of this release. These statements include those related to sponsored research activities to be conducted at UofL the timing of the related clinical trials (if any). Actual events or results may differ from the Company's expectations. For example, there can be no assurance that clinical trials will be applied for by or approved to begin by any projected timeline or will proceed as contemplated by any projected timeline; that the Company will successfully develop any drugs or therapeutic devices; that preclinical or clinical development of the Company's drugs or therapeutic devices will be successful; that future clinical trial data will be favorable or that such trials will confirm any improvements over other products or lack negative impacts; that any drugs or therapeutic devices will receive required regulatory approvals or that they will be commercially successful; that patents will issue on the Company's owned and in-licensed patent applications; that such patents, if any, and the Company's current owned and in-licensed patents would prevent competition; that the Company will be able to procure or earn sufficient working capital to complete the development, testing and launch of the Company's prospective therapeutic products; that the Company will be able to maintain or

expand market demand and/or market share for the Company's diagnostic products generally, particularly in view of COVID-19-related deferral of patients' physician-office visits and FastPack reimbursement pricing challenges; that adoption and placement of FastPack PRO System instruments (which are the only FastPack instruments on which the Company's SARS-CoV-2 IgG test kits can be run) will be widespread; that the Company will be able to manufacture the FastPack PRO System instruments and SARS-CoV-2 IgG test kits successfully; that any commercialization of the FastPack PRO System instruments and SARS-CoV-2 IgG test kits will be profitable; or that the FDA will ultimately approve an Emergency Use Authorization for the Company's SARS-CoV-2 IgG test. The Company's stock price could be harmed if any of the events or trends contemplated by the forward-looking statements fails to occur or is delayed or if any actual future event otherwise differs from expectations. Additional information concerning these and other risk factors affecting the Company's business (including events beyond the Company's control, such as epidemics and resulting changes) can be found in the Company's prior filings with the Securities and Exchange Commission, available at www.sec.gov. The Company disclaims any intent or obligation to update these forward-looking statements beyond the date of this news release, except as required by law. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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