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Qualigen Therapeutics Engages STA Pharmaceutical as GMP Manufacturer of AS1411 for Clinical Trials

CARLSBAD, Calif., Nov. 5, 2020 /PRNewswire/ -- **Qualigen Therapeutics, Inc.** (Nasdaq: QLGN) announced today it has signed a contract with STA Pharmaceutical Co., Ltd. (WuXi STA), a subsidiary of WuXi AppTec, for GMP production of AS1411, Qualigen's lead drug candidate for the treatment of COVID-19 and other viral diseases, for potential clinical trials. Preclinical studies at the University of Louisville's (UofL) Center for Infectious Disease have demonstrated the ability of AS1411, a novel aptamer-based molecule, to protect cells from the damaging effects of the novel coronavirus.

"With its industry leading large-scale oligonucleotide manufacturing capability, this new manufacturing contract with WuXi STA will ensure we have adequate supply of AS1411 for our anticipated clinical trials in patients with COVID-19. Securing multisource manufacturing capacity is an integral part of our planning for this potential broad antiviral therapeutic," said Michael Poirier, President, Chief Executive Officer and Chairman of Qualigen. "Given the persistence of the pandemic, there continues to be a need to develop treatments for COVID-19. We are encouraged by the AS1411 preclinical data indicating potential effectiveness against SARS-CoV-2, the novel coronavirus that causes COVID-19. Moreover, AS1411 has a strong safety profile as it was previously administered to more than 100 patients with advanced cancers and was well tolerated with no evidence of severe side effects."

In June 2020, Qualigen signed an exclusive license agreement with UofL for U.S. patent rights covering the treatment of COVID-19 with AS1411. Qualigen intends to work with UofL to complete investigational new drug (IND)-enabling studies and plans to file an IND application with the U.S. Food and Drug Administration in early calendar 2021. Qualigen's aim is to initiate a Phase 2a clinical study in COVID-19 patients in the first half of calendar 2021.

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 nucleolin-targeting DNA aptamer of ALAN, AS1411, is also being studied as a drug candidate for use in treating COVID-19 and other viral-based infectious diseases. 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 the timing of the filing and (if any) acceptance of an IND application for AS1411 against COVID-19 and the timing of the related clinical trials (if any), and the availability and adequacy of supply of AS1411 for anticipated clinical trials. Actual events or results may differ from the Company's expectations. For example, there can be no assurance that clinical trials will be approved to begin by 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 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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