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Qualigen Therapeutics Completes Recertification of Existing AS1411 Drug Supply for Use in Upcoming Clinical Trials

CARLSBAD, Calif., Dec. 2, 2020 /PRNewswire/ -- **Qualigen Therapeutics, Inc. (Nasdaq: QLGN)** announces that it has completed the recertification of its supply of AS1411, and has begun final formulation and filling for use in the Company's proposed Phase 2a efficacy trials of AS1411 for the treatment of patients with COVID-19. Qualigen plans to seek U.S. Food and Drug Administration (FDA) approval for and to begin these trials in the first half of calendar 2021.

Qualigen's lead compound AS1411 is a nucleolin-targeting DNA aptamer drug candidate for the treatment of COVID-19 and other viruses. Preclinical studies at the University of Louisville's (UofL) Center for Infectious Disease have demonstrated the ability of AS1411 to protect cells from the damaging effects of the novel coronavirus. In addition, AS1411 holds potential as a broad antiviral therapeutic agent, which could expand its applications and market potential.

"Even with the roll-out of COVID-19 vaccines, we see this virus being around for many years to come in different forms. The mechanism by which AS1411 is believed to work, by blocking the ability of viruses to replicate in the body, may make our therapeutic effective against future mutations in COVID-19 as well as against other dangerous viruses including the flu," stated Michael Poirier, President, Chief Executive Officer and Chairman of Qualigen.

Mr. Poirier added: "Recertification of our AS1411 inventory represents another critical step in advancing our antiviral development program in a cost-efficient manner. We continue to move forward with our IND-enabling studies and are on track to commence the efficacy stage of human trials in the first half of next year, upon obtaining IND approval from the FDA. We believe there is great potential for this drug to be an effective therapeutic for COVID-19, in addition to other viral infections."

In June 2020, Qualigen signed an exclusive license agreement with UofL for U.S. patent rights covering the treatment of COVID-19 with AS1411, adding to Qualigen's other AS1411 license exclusivities. Qualigen intends to work with UofL to complete investigational new drug (IND)-enabling studies and plans to file an IND application with the FDA 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 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 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 potential future development, testing, efficacy, approval, manufacturing and commercialization of product candidates, including the possible effectiveness of AS1411 against COVID-19 or other viral infections and the approval and timing of 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 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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