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# Qualigen Therapeutics Announces Filing of U.S. Provisional Patent Application for the Use of AS1411 to Prevent Viral Infections

## Protects potential expanded use of AS1411 to prevent coronavirus transmission, including SARS-CoV-2

CARLSBAD, Calif., Sept. 17, 2020 /PRNewswire/ --**Qualigen Therapeutics, Inc.** (Nasdaq: QLGN) announces its and the University of Louisville's joint filing of a United States provisional patent application, entitled "Methods of inhibiting or treating coronavirus infection, and methods for delivering an anti-nucleolin agent." The application was filed in conjunction with Drs. Paula J. Bates and Kenneth E. Palmer from the University of Louisville, and covers methods for using the antiviral drug candidate AS1411 to prevent SARS-CoV-2 (the virus that causes COVID-19) from entering the body through mucous membranes in the nose, mouth and eyes.

As stated in the patent application, Qualigen believes that AS1411 could be administered by means of inhalers, nose spray or eye drops to individuals who have recently come in contact with SARS-CoV-2, or are at high risk of contracting the virus. As such, AS1411 could serve as a protective defense or prophylaxis against this and possibly other viral-based diseases such as seasonal influenza.

"This provisional patent application, if granted, would provide Qualigen with additional intellectual property protection for an expanded use of AS1411 and other nucleolin-binding DNA aptamers not only to treat viral infections like COVID-19, but also to prevent such diseases in the first place by stopping the viruses from infecting and doing damage to the lungs and other vital areas of the body," stated Michael Poirier, President, Chief Executive Officer and Chairman of Qualigen. "While this is still an early hypothesis, virus infection prevention represents a very broad and exciting application for our technology."

Qualigen intends to work with the University of Louisville to complete investigational new drug (IND)-enabling studies of AS1411 as a therapeutic against COVID-19 and plans to file an IND application with the U.S. Food and Drug Administration in the fourth quarter of 2020. The intent is to commence Phase 1/2 clinical studies in COVID-19 patients in early 2021. The Company plans to collaborate with the University of Louisville to further study the possible separate use of AS1411 for virus infection prevention.

### **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 the possible effectiveness of AS1411 as a prophylaxis against COVID-19 or other viral diseases, the possibility of patent protection for such use, the timing of the filing and (if any) acceptance of an IND application for AS1411 as a therapy against COVID-19 and 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 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](http://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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