July 1, 2020

Qualigen Therapeutics Submits Notification to FDA to Commence Distribution of its FastPack® COVID-19 Antibody Test

CARLSBAD, Calif., July 1, 2020 /PRNewswire/ --**Qualigen Therapeutics, Inc.** (NASDAQ: QLGN) ("Qualigen" or the "Company") announces it has submitted an official notification to the U.S. Food and Drug Administration ("FDA") to commence sales in the U.S. of the Company's FastPack® SARS-CoV-2 IgG test for COVID-19 antibodies. This test has already been submitted to the FDA for Emergency Use Authorization ("EUA"), but the notification enables Qualigen to commence sales even before the FDA considers or formally grants the EUA for the test. Qualigen expects sales and shipments of the new test to begin in mid-July.

The FastPack® COVID-19 antibody test is a chemiluminescent microparticle test intended for the qualitative detection (i.e., yes/no) of SARS-CoV-2 IgG antibodies in blood to identify individuals with an adaptive immune response to the virus that causes COVID-19, indicating recent or prior infection of the disease (which, as a practical matter, is believed to be indicative of immunity against re-infection). Qualigen's FastPack® test uses a specific protein that is also used by major diagnostics companies including Abbott Laboratories, Roche Diagnostics and Bio-Rad Laboratories in their COVID-19 antibody tests. The important advantage of FastPack® over testing in large commercial laboratories, however, is its ability to deliver accurate results far more rapidly, in this case under 10 minutes, in physician offices, clinics and hospitals.

"Of the different options available, we chose to develop a test specific to the IgG antibody because IgG represents the long-term immune response. We believe our test's combination of high speed and high accuracy provides the clinician with more useful and actionable information than other testing approaches," Michael Poirier, the Company's CEO, explained. "We believe that reliable, yet convenient testing at the point-of-care is critical to helping combat this virus and get Americans back to their normal routines."

The new test is designed for use with Qualigen's new FastPack® PRO System point-of-care diagnostic instruments. The FastPack® PRO System is an upgraded version of Qualigen's flagship FastPack® IP rapid immunoassay diagnostic point-of-care system.

Qualigen has been producing high-quality diagnostic testing products for almost 20 years, and has established a strong reputation for delivering highly accurate point-of-care tests that help save people's lives.

About the FastPack® System

The FastPack® System is a rapid and highly accurate immunoassay testing system consisting of the FastPack® Analyzer and the FastPack® test pouch (a single-use, disposable, foil packet that includes the FastPack® reagent chemistry). This "Laboratory in a Pouch" is installed in physician offices, clinics and small hospitals around the world, and quickly detects diseases and medical conditions at the point-of-care. Since the conception of the system, the Company has expanded its assay menu to 10 tests including tests for prostate cancer, thyroid function, metabolic disorders, antibodies against SARS-CoV-2, and research applications. Over the past 20 years, FastPack® has generated more than $100 million in commercial sales. Qualigen's worldwide distributor for FastPack® is Sekisui Diagnostics, LLC, a subsidiary of a multibillion-dollar Japanese chemical and technology company; Sekisui, in turn, works with national distributors including McKesson Corporation and Henry Schein Inc.

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 FastPack® menu includes tests for cancer, men's health, hormone function, vitamin D status and antibodies against SARS-CoV-2. The Company's cancer therapeutics pipeline includes ALAN (AS1411-GNP), RAS-F3 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 viral-based infectious diseases, including COVID-19. RAS-F3 is a small molecule RAS oncogene protein-protein inhibitor for blocking RAS mutations that lead to tumor formation, especially in pancreatic, colorectal and lung cancers. STARS™ is a DNA/RNA-based treatment device for removal from circulating blood of precisely targeted tumor-produced and viral compounds. 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/.

Qualigen 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 and launch of product candidates. Actual events or results may differ from our expectations. For example, there can be no assurance 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; 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's request to the FDA for Emergency Use Authorization will

ultimately be approved; 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 we will be able to procure or earn sufficient working capital to complete the development, testing and launch of our prospective therapeutic products; or that we will be able to maintain or expand market demand and/or market share for our diagnostic products. Our 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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