July 30, 2020

Qualigen Therapeutics Begins Shipping FastPack® COVID-19 Antibody Test

CARLSBAD, Calif., July 30, 2020 /PRNewswire/ --**Qualigen Therapeutics, Inc.** (NASDAQ: QLGN) (Qualigen or the Company) announced today it has begun commercial shipments of its FastPack® SARS-CoV-2 IgG diagnostic test for COVID-19 antibodies. This test has been submitted to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA), and earlier this month the Company submitted an official notification to the FDA of its plans to exercise its right to commence sales while the EUA is pending.

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. Prior infection is presumed to be indicative of immunity against re-infection for at least some period of time.

The COVID-19 antibody test is designed for use with Qualigen's new FastPack PRO System, a point-of-care diagnostic instrument. The FastPack PRO System is an upgraded version of Qualigen's flagship FastPack IP rapid immunoassay diagnostic system – in essence, a "lab in a box" that allows test results to be delivered with the accuracy of large laboratories but much more rapidly. Unlike tests at reference laboratories, the FastPack tests are conducted in physician offices, clinics and hospitals, and provide results in approximately 10 minutes. The Company announced earlier this month that a portion of the proceeds from its recent funding will be used to increase production of the FastPack PRO System.

"We are pleased to start shipping our FastPack PRO systems and serology tests for COVID-19 antibodies, and expect to see a ramp-up of production through the end of the year," stated Michael Poirier, President, Chief Executive Officer and Chairman of Qualigen. "Testing for SARS-CoV-2 IgG antibodies is likely to be critical to fighting this disease for years to come, not only in this early stage of tracking and tracing, but also in time to prioritize vaccine deployment. We believe our rapid diagnostics offering provides accurate results for clinicians to have more timely and actionable information than other testing approaches can provide."

Qualigen has been producing high-quality diagnostic testing products for nearly 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 diagnostic testing system consisting of a FastPack analyzer and a FastPack test pouch (a single-use, disposable foil packet that includes the FastPack reagent chemistry). Installed in physician offices, clinics and small hospitals around the world, the system 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 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 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. The FastPack System menu includes 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 and launch of product candidates. Actual events or results may differ from our expectations. For example, there can be no assurance that adoption and placement of FastPack PRO System instruments (which are the only FastPack instruments on which the Company's SARS-CoV-2 IgG and cFN test kits can be run) will be widespread; that the Company will be able to manufacture the FastPack PRO System instruments and the 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 the FDA will ultimately approve an Emergency Use Authorization for the Company's SARS-CoV-2 IgG test; 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 clinical trials will be approved to begin by or will actually begin by or will proceed as contemplated by any projected timeline; 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; and 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. 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.

View original content:http://www.prnewswire.com/news-releases/qualigen-therapeutics-begins-shipping-fastpack-covid-19-antibody-test-301102853.html

SOURCE Qualigen, Inc.