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Qualigen Therapeutics Releases FastPack® SARS-CoV-2 Antibody Diagnostic Test to University of Louisville to Conduct Validation Studies

CARLSBAD, Calif., June 2, 2020 /PRNewswire/ -- **Qualigen Therapeutics, Inc.** (NASDAQ: QLGN) (Qualigen or the Company) announced today that the Company has released a pre-launch supply of its proposed FastPack® SARS-CoV-2 IgG Immunoassay diagnostic test kits to the University of Louisville to conduct validation studies with hundreds of patient samples, as well as for use in research on COVID-19. SARS-CoV-2 is the virus that causes COVID-19.

Qualigen's SARS-CoV-2 IgG immunoassay, for use with its new FastPack PRO System point-of-care diagnostic instruments, is a chemiluminescent microparticle test intended for the qualitative detection (i.e., yes/no) of the presence of SARS-CoV-2 IgG antibodies in blood. The FastPack PRO System is an upgraded version of Qualigen's flagship FastPack IP rapid immunoassay diagnostic point-of-care system.

"This is an important step in the evolution of SARS-CoV-2 antibody testing, given the high number of inaccurate tests in the marketplace," said Michael Poirier, President, Chief Executive Officer and Chairman of Qualigen. "Reliable, accurate and rapid testing for the presence of antibodies is critical to understanding who may have been infected with SARS-CoV-2 and who could potentially have an immune response to re-infection."

Mr. Poirier continued, "Since its founding in my basement in Minnesota over 20 years ago, Qualigen has been continuously advancing this sophisticated rapid diagnostic technology, which is now used in physician offices, clinics and small hospital worldwide. I believe Qualigen is well suited to bring to market diagnostic systems that can improve our understanding and tracking of this disease as we strive to open up the U.S. economy."

Kenneth Palmer, PhD, Director of the University of Louisville Center for Predictive Medicine for Biodefense and Emerging Infectious Diseases (CPM), and his research team will be conducting analytical validation studies on the FastPack SARS-CoV-2 IgG Immunoassay to provide Qualigen with validation data to submit to the U.S. Food and Drug Administration (FDA) requesting Emergency Use Authorization. The University of Louisville's CPM is one of only 12 infectious disease biocontainment facilities in the United States and is on the forefront of COVID-19 and infectious disease research.

"The ability to obtain rapid, accurate SARS-CoV-2 antibody data at the point of care for timely assessment of a patient's status is vital to the next phase of this pandemic. We are excited to be working with Qualigen on this important project," added Dr. Palmer.

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 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.

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 and vitamin D status. 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. 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. or to order FastPack diagnostic products, 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 the validation studies for the proposed FastPack® SARS-CoV-2 IgG Immunoassay diagnostic test kits will be timely conducted or will provide favorable validation data; that any request to the FDA for Emergency Use Authorization will be granted; that the Company will be able to manufacture the FastPack Pro System instruments and test kits successfully; that any commercialization of the FastPack Pro System instruments and test kits will be profitable; that the Company will successfully develop any drugs or therapeutic devices; that preclinical or clinical development 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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