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Qualigen Therapeutics Announces Completion of Milestone Related to the License and Technology Transfer of its FastPack® Diagnostics Products in China

CARLSBAD, Calif., Jan. 26, 2021 /PRNewswire/ --**Qualigen Therapeutics, Inc.** (Nasdaq: QLGN), a biotechnology company focused on developing novel therapeutics for the treatment of cancer and viral diseases, announces achievement of a milestone event which triggered a payment obligation from Yi Xin Zhen Duan Jishu (Suzhou) Ltd. of Suzhou, China (Yi Xin) to Qualigen. The milestone event pertained to the initiation of technology transfer of Qualigen's core FastPack® System, a rapid and highly accurate immunoassay testing system consisting of the FastPack Analyzer and the FastPack single-use, disposable test pouch.

Under the terms of an agreement announced in October 2020, Yi Xin will develop, manufacture and sell new generations of diagnostic test systems based on Qualigen's core FastPack® "laboratory in a pouch" technology, which includes high throughput diagnostic systems. In addition, Yi Xin will have the rights to manufacture and sell Qualigen's current generations of rapid point-of-care FastPack diagnostic products in China. The agreement called for net cash payments to Qualigen in the fourth quarter of calendar 2020 and the first quarter of calendar 2021 totaling in the mid- to high-hundreds of thousands of dollars, and Qualigen is also eligible to receive low- to mid-single-digit royalties on net sales.

"Yi Xin provides entrée to the China market for our patented FastPack diagnostics product line and we are encouraged by the strong start to this alliance," stated Michael Poirier, Chairman, Chief Executive Officer and President of Qualigen. "This collaboration represents an expansion opportunity with additional resources to grow the FastPack line in an efficient manner while we advance our therapeutics pipeline focused on the treatment of cancer and viral-based diseases toward clinical trials this year."

"Accurate testing at the point of patient care is becoming increasingly important across China to achieve better patient outcomes and utilize healthcare resources more efficiently. We are looking forward to launch the current FastPack product and developing new generations of the FastPack system that include a high-volume system analyzer for use in large hospitals and reference laboratories," said Peng Zhou, President and Chief Executive Officer of Yi Xin.

About Qualigen Therapeutics, Inc.

Qualigen Therapeutics, Inc. is a biotechnology company focused on developing novel therapeutics for the treatment of cancer and viral 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 expected payments to the Company under the Yi Xin agreement and Yi Xin's future development, manufacturing and sales activities. Actual events or results may differ from the Company's expectations. For example, there can be no assurance that Yi Xin's future development, manufacturing and sales activities will proceed as anticipated or that Yi Xin (which is a newly-formed company) will be able to honor its contractual obligations to the Company; that clinical trials will be applied for by or approved to begin by any projected timeline 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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