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Qualigen Therapeutics, Inc. Announces Submission of Investigational New Drug (IND) Application for QN-165, for the Treatment of COVID-19

CARLSBAD, Calif., July 14, 2021 (GLOBE NEWSWIRE) -- Qualigen Therapeutics, Inc. (NASDAQ: QLGN), a biotechnology company focused on developing novel therapeutics for the treatment of cancer and viral diseases, announced today the submission of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for Qualigen's QN-165 with an initial target indication for the treatment of COVID-19 in hospitalized patients. QN-165, a DNA aptamer, is a broad-based antiviral drug candidate that has exhibited antiviral activity in multiple in vitro assays against different viruses.

“We are excited to have reached this important milestone of submitting our first IND application to the FDA on our most advanced therapeutics program. This submission of the IND application for Phase 1b/2a clinical trials for QN-165 represents another step in our evolution from a globally patented and commercially successful diagnostics company to a clinical-stage therapeutics company with multiple programs,” stated Michael Poirier, Chairman and Chief Executive Officer at Qualigen Therapeutics.

Poirier added, “QN-165 is a unique drug candidate that has a completely different approach to attacking a virus, which we think will enable it to work against all virus strains and variants. QN-165 is a piece of synthetic DNA that does not attack the coronavirus directly. Instead, it targets and binds to the nucleolin protein and can enter cells that overexpress nucleolin. Viruses such as SARS-CoV-2 exploit nucleolin to gain access to a cell and manipulate it for its own viral replication purposes. We believe that QN-165, by tying up nucleolin, blocks that mechanism and prevents the virus replication process. Therefore, even if the virus mutates, we do not expect this to decrease the effectiveness of QN-165. The reason is that QN-165 targets nucleolin instead of the virus itself. We believe that this approach will set QN-165 apart and has the potential for QN-165 to be proven effective against a multitude of viral mutations, including all of the strains and variants of the novel coronavirus.”

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 20 years. Our cancer therapeutics pipeline includes QN-247, RAS-F, and STARS™. QN-247 (formerly referred to as ALAN) is a DNA coated gold nanoparticle cancer drug candidate that has the potential to target various types of cancer with minimal side effects; the nanoparticle coating technology is similar to the core nanoparticle coating

technology used in our blood-testing diagnostic products. The foundational aptamer of QN-247, QN-165, is also a drug candidate for treating COVID-19 and other viral-based infectious diseases; we currently plan that our first therapeutics clinical trial would be the trial of QN-165 for treatment of COVID-19 in hospitalized patients. (QN-165 was formerly referred to as AS1411.) 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.

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 Company's prospects and strategy for the development of therapeutic drug candidates and the potential focused and general effectiveness of QN-165 against viruses. Actual events or results may differ from the Company's expectations. For example, there can be no assurance that the FDA will approve the Company's IND application, soon or at all; that clinical trials (including the contemplated QN-165 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 QN-165 will be demonstrated to be safe and effective against either the initial version of SARS-CoV-2 or of any other virus, or against any strains or variants thereof; 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; or that the Company will be able to maintain or expand market demand and/or market share for the Company's diagnostic products. 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 can be found in the Company's prior filings with the Securities and Exchange Commission, including its most recent Form 10-K, all of which 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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