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Todos Medical Launches Phase 2 Clinical Trial of Its Antiviral 3CL Protease Inhibitor NLC-V-01 (Tollovir) in Hospitalized COVID-19 Patients

- *First 10 patients dosed in 77 patient randomized, double blind, placebo controlled Phase 2 Clinical Trial at Shaare Zedek Medical Center in Jerusalem, Israel*
- *Data from randomized, placebo controlled, open label Phase 1b trial in 27 hospitalized COVID-19 patients supports dose selection for the Phase 2 Clinical Trial*
- *Company to include its proprietary 3CL protease enzymatic assay ("TolloTest™) as exploratory theranostic biomarker*

NEW YORK, NY, and REHOVAT, ISRAEL, April 19, 2021 (GLOBE NEWSWIRE) -- via NewMediaWire -- **Todos Medical, Ltd. (OTCQB: TOMDF)**, a comprehensive medical diagnostics and related solutions company, today announced the initiation of a randomized, double blind, placebo-controlled Phase 2 clinical trial (the "Clinical Trial") of its antiviral NLC-V-01 ("Tollovir™"), a potent 3CL protease inhibitor, for the treatment of hospitalized COVID-19 patients. The trial, being conducted at Shaare Zedek Medical Center in Jerusalem, Israel, will evaluate the safety and efficacy of Tollovir for the treatment of COVID-19 in hospitalized patients. Tollovir is a patent-pending therapeutic agent being developed through a joint venture between Todos Medical and NLC Pharma. 3CL protease inhibitors are targeted as desirable candidates for development of antiviral therapies against SARS-CoV-2 (the virus that causes COVID-19).

The primary endpoints of the Clinical Trial being examined are:

- Time to discharge from the hospital
- Time to clinical improvement based upon the National Early Warning Score 2 (NEWS2) in Israel

The secondary endpoints of Clinical Trial being examined are:

- Rate of change of measured parameters
- Rate of change in vital signs (blood pressure, heart rate, respiratory rate, saturation, and body temperature)
- Time from the 1st day of receiving NLC-V treatment to negative RT-PCR test result
- COVID-19 related deaths
- Incidence of deterioration and need for mechanical ventilation
- Incidence and duration of time on supplemental oxygen

A synopsis of the Clinical Trial is available on the Israel Ministry of Health's website

at: https://my.health.gov.il/CliniTrials/Pages/MOH_2021-01-20_009687.aspx

Commenting on the Phase II trial, Dr. Dorit Arad, Co-Founder and Chief Scientific Officer of NLC Pharma, stated, “The launch of this Clinical Trial is a critical step towards the clinical validation of our proprietary scientific work that was recently further supported with data from the Dan Peer laboratory at Tel Aviv University in Israel concluding that our proprietary medical grade 3CL protease inhibitor, Tollovir, is an antiviral therapeutic candidate for SARS-CoV-2’s based on its 3CL protease reproduction mechanism. I am glad that my pioneering academic work over the last 30 years on 3CL mechanisms has made such a significant impact, and that it is finally being recognized by leading pharmaceutical companies as a key target in the war against COVID-19 that could yield an easy to administer oral antiviral therapeutic capable of stopping SARS-CoV-2 replication, independent of different mutations that are emerging at the site of spike protein.”

Dr. Arad continued, “In 2020, we enrolled 27 patients who participated in a Phase 1b open-label, placebo controlled observational study in Israel of various formulations of this antiviral therapeutic candidate, and we also received feedback from patients all over the world who used certain dietary supplement formulations of our 3CL inhibitors to combat COVID-19 infection. Based on the data gathered from those two sources, we strongly believe that the further development of the selected formulation, Tollovir, is justified as a potential clinical therapeutic for significantly reducing the severity of a COVID-19 infection, and ultimately may be proven in further studies to be a prophylactic to reduce the risk of getting COVID-19 upon SARS-CoV-2 exposure.”

“The solid peer-reviewed scientific evidence regarding 3CL protease inhibitors as antiviral drugs against coronaviruses, together with recent *in vitro* data generated at Tel Aviv University that we reviewed in detail showing Tollovir’s activity of inhibiting SARS-CoV-2 replication, and quite importantly, a review of the empirical data from people using the dietary supplement in hospitalized settings all strongly encourage us to perform this Phase 2 study. The goal is to provide results that could have a significant impact on our ability to treat hospitalized patients diagnosed with COVID-19,” said Dr. Rokach, MD Lung Specialist and Principal Investigator of the Clinical Trial at Shaare Zedek Medical Center in Jerusalem.

“We are excited by the initiation of this clinical trial for Tollovir,” said Gerald E. Commissiong, President & CEO of Todos. “Dr. Arad’s history with this therapeutic target is well-known throughout the field of coronavirus research, and Todos is proud to support this very important clinical development program at a time when emerging variants are potentially threatening the progress that has been made in the last year as the field focused on COVID-19 vaccine development. By impacting SARS-CoV-2’s ability to reproduce in the body, we are hopeful to improve hospitalized patients’ clinical outcomes significantly, while also limiting the virus’ ability to mutate by reducing the number of times it is able to replicate in a host. Additionally, our TolloTest™ assay, currently optimized for inpatient settings, could be a valuable biomarker for measuring a person’s contagiousness by quantitatively measuring 3CL protease as a proxy for viral load, which could provide clearer objective data to make end of quarantine decisions when many PCR positive patients are likely inappropriately released from quarantine and able to infect others.”

For information related to Todos Medical’s COVID-19 testing capabilities, please visit www.todoscovid19.com.

For testing and PPE inquiries, please email sales@todosmedical.com.

About Todos Medical Ltd.

Founded in Rehovot, Israel with offices in New York City, Todos Medical Ltd. (OTCQB: TOMDF), engineers life-saving diagnostic solutions for the early detection of a variety of cancers. The Company's state-of-the-art and patented Todos Biochemical Infrared Analyses (TBIA) is a proprietary cancer-screening technology using peripheral blood analysis that deploys deep examination into cancer's influence on the immune system, looking for biochemical changes in blood mononuclear cells and plasma. Todos' two internally-developed cancer-screening tests, TMB-1 and TMB-2, have received a CE mark in Europe. Todos recently entered into an exclusive option agreement to acquire U.S.-based medical diagnostics company Provista Diagnostics, Inc. to gain rights to its Alpharetta, Georgia-based CLIA/CAP certified lab currently performing PCR COVID testing and Provista's proprietary commercial-stage Videssa® breast cancer blood test. The transaction is expected to close in the third quarter of 2020.

Todos is also developing blood tests for the early detection of neurodegenerative disorders, such as Alzheimer's disease. The Lymphocyte Proliferation Test (LymPro Test™) is a diagnostic blood test that determines the ability of peripheral blood lymphocytes (PBLs) and monocytes to withstand an exogenous mitogenic stimulation that induces them to enter the cell cycle. It is believed that certain diseases, most notably Alzheimer's disease, are the result of compromised cellular machinery that leads to aberrant cell cycle re-entry by neurons, which then leads to apoptosis. LymPro is unique in the use of peripheral blood lymphocytes as a surrogate for neuronal cell function, suggesting a common relationship between PBLs and neurons in the brain.

Todos has entered into distribution agreements with companies to distribute certain novel coronavirus (COVID-19) test kits. The agreements cover multiple international suppliers of PCR testing kits and related materials and supplies, as well as antibody testing kits from multiple manufacturers after completing validation of said testing kits and supplies in its partner CLIA/CAP certified laboratory in the United States. Todos has formed a strategic partnership with Integrated Health LLC to deploy mobile COVID-19 testing in the United States. Additionally, Todos has entered into a joint venture with NLC Pharma to pursue the development of diagnostic tests targeting the 3CL protease, as well as 3CL protease inhibitors that target the reproductive mechanism of coronaviruses.

For more information, please visit https://www.todosmedical.com/.

Forward-looking Statements

Certain statements contained in this press release may constitute forward-looking statements. For example, forward-looking statements are used when discussing our expected clinical development programs and clinical trials. These forward-looking statements are based only on current expectations of management, and are subject to significant risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements, including the risks and uncertainties related to the progress, timing, cost, and results of clinical trials and product development programs; difficulties or delays in obtaining regulatory approval or patent protection for product candidates; competition from other biotechnology companies; and our ability to

obtain additional funding required to conduct our research, development and commercialization activities. In addition, the following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: changes in technology and market requirements; delays or obstacles in launching our clinical trials; changes in legislation; inability to timely develop and introduce new technologies, products and applications; lack of validation of our technology as we progress further and lack of acceptance of our methods by the scientific community; inability to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties that may develop with our process; greater cost of final product than anticipated; loss of market share and pressure on pricing resulting from competition; and laboratory results that do not translate to equally good results in real settings, all of which could cause the actual results or performance to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, Todos Medical does not undertake any obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting Todos Medical, please refer to its reports filed from time to time with the U.S. Securities and Exchange Commission.

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