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Todos Medical Provides Update on COVID-19 Oral Antiviral 3CL Protease (Main Protease) Inhibitor Tollovir Clinical Development Program in Light of Molnupiravir Clinical Trial Data from Merck

New York, NY, and Tel Aviv, ISRAEL, Oct. 04, 2021 (GLOBE NEWSWIRE) -- via NewMediaWire -- **Todos Medical, Ltd. ("Todos Medical") (OTCQB: TOMDF)** a comprehensive medical diagnostics and related solutions company, today provided an update on its COVID-19 oral antiviral 3CL protease ("Main Protease", or "Mpro") inhibitor Tollovir® clinical development program currently enrolling a Phase 2 clinical trial in hospitalized patients at Shaare Zedek Medical Center in Jerusalem, Israel. In light of the Data Safety Monitoring Board (DSMB) overseeing Merck's trial in consultation with the US Food & Drug Administration (FDA) stopping enrollment after an interim analysis of 775 patient revealed a 50% reduction in the risk of hospitalization and death in unvaccinated outpatient COVID-19 patients recruited into Merck's Phase 3 clinical trial within 5 days of symptom onset, Todos has now begun a thorough re-evaluation of outpatient trial designs to provide the fastest path to bring Tollovir to market in the outpatient setting given the now significantly lower than expected patient enrollment threshold required to demonstrate efficacy.

There are currently 27 patients enrolled in the 77-patient Tollovir hospitalized clinical trial in Israel. A pre-specified interim analysis of the safety and efficacy data of Tollovir is scheduled at 33 patients, which the Company expects to enroll in the next several weeks. Upon enrollment completion of the course of treatment for the 33rd patient, the Tollovir DSMB will convene to review the data and decide whether continued enrollment in the clinical study is warranted. Additional clinical trial sites that currently have higher volumes of COVID patients in Israel are expected to be added to the study in order to accelerate enrollment.

Tollovir is a proprietary formulation of key plant extracts that contain potent, highly selective, natural 3CL protease (Mpro) inhibitor & anti-cytokine activities that make Tollovir a strong therapeutic candidate for the treatment of COVID-19. The ingredients contained within Tollovir have been deemed safe for widespread use by multiple regulatory agencies worldwide, including the US FDA, and have been used in over 5,000 human subjects since the beginning of the COVID-19 pandemic, with certain case studies previously shared publicly. Other oral antiviral drug candidates for COVID-19, such as Merck's Molnupiravir and Pfizer's PF-07321332, are chemical compounds that have yet to be deemed safe for widespread human use by any regulatory agency. Given the strong safety profile of Tollovir,

the Company believes it provides a compelling alternative to newly created or repurposed failed chemical drug candidates that have yet to rigorously demonstrate long-term safety.

“Together with NLC Pharma, our joint venture and co-development partner in Tollovir, we were pleasantly surprised with the Molnupiravir DSMB’s decision to halt enrollment in Merck’s clinical study at the pre-specified interim analysis point after showing a 50% reduction in hospitalization and death based on 775 enrolled patients,” said Gerald Commissiong, President & CEO of Todos Medical. “While it is a tremendous outcome for patients with COVID-19 and the worldwide community at large to have an oral antiviral demonstrate a statistically significant reduction in the most severe outcomes of this devastating disease, it is clear to us from the data we have seen that this decision was likely driven more by the tremendous need in the market for an oral antiviral therapy than by the data itself for this mutagenesis-based drug candidate given the scarcity of available safety data available for Molnupiravir in COVID-19, and the relatively restrictive entry criteria required for its Phase 3 clinical trial.”

On September 30, 2021, Todos announced results from an observational clinical study conducted in Israel by NLC Pharma. Results from this observational study are outlined below:

	Tollovir® group	**Observed group**
Age (range)	45-87	60-90
Age (Mean)	75	73
Hospitalization Days (range)	6-19	4-41
Hospitalization Days (mean)	13.3	17.4
Died in hospital	0	5
Deteriorated to respirator and recovered	0	3
High CRP serum levels at hospitalization	10	20
CRP reduction of 50% and more within 48-72 hours	5 (50%)	2 (10%)

Dr. Dorit Arad, Chief Scientific Officer of NLC Pharma commented, “Our biggest hurdle in being able to finalize a full development program for Tollovir in the outpatient setting has been trying to decipher what regulators are likely to accept as an approvable endpoint with regards to safety and efficacy. Given the actions of the DSMB in stopping the trials, coupled with the positive comments heard from Dr. Fauci and Dr. Scott Gottlieb with regards to the efficacy demonstrated by Molnupiravir, we are now very comfortable that we have a comparator product against which to build our endpoints for Tollovir. We now intend to engage with regulators in India as well as in Israel, where we are currently enrolling a double blind placebo controlled Phase 2 clinical study in hospitalized patients with a pending interim data readout, to discuss how we can now finalize a pivotal outpatient trial design(s) and begin to move forward rapidly with enrollment as we also prepare for a pre-IND meeting with US FDA that will be followed by a well-defined US clinical development program.”

For more information, please visit www.todosmedical.com. For more information on the Company’s CLIA/CAP certified lab Provista Diagnostics, Inc. please visit www.provistadx.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. In 20201, Todos completed the acquisition of 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 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 is focused on the commercialization of Videssa and will bring the TBIA tests to market thereafter.

Todos has entered into a joint venture with NLC Pharma targeting diagnostic and testing solutions to address the COVID-19 pandemic. The Joint-Venture is pursuing the development of diagnostic tests targeting the 3CL protease, as well as 3CL protease inhibitors that target a fundamental reproductive mechanism of coronaviruses. The Company’s proprietary therapeutic candidate Tollovir™ is currently in a Phase 2 clinical trial to treat hospitalized COVID-19 patients in Israel, and is preparing to initiate Phase 2/3 clinical trials for both hospitalized and non-hospitalized patients in Israel.

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 is also distributing certain (COVID-19) testing materials and supplies to CLIA-certified labs in the United States. The products cover multiple suppliers of PCR testing kits, extraction kits, automation materials and supplies, as well as COVID-19 antibody and antigen testing kits.

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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