

September 30, 2021



Todos Medical Announces Positive Observational Trial Results for Oral Antiviral 3CL Protease (MPro) Inhibitor Tollovir®

- ***Treatment group participants experienced a reduction in key inflammatory biomarker***
- ***Observed a reduction in time of hospitalization and death rate with no deaths recorded in treatment group***

New York, NY, and Tel Aviv, ISRAEL, Sept. 30, 2021 (GLOBE NEWSWIRE) -- via [NewMediaWire](#) -- **Todos Medical, Ltd. ("Todos Medical") (OTCQB: TOMDF)** a comprehensive medical diagnostics and related solutions company, today announced results from an observational study of 32 hospitalized COVID-19 patients treated with Tollovir®, the Company's proprietary oral antiviral 3CL protease inhibitor treatment. This exploratory study of 11 treated patients was compared with 21 randomly selected untreated patients in the hospitalized setting who had similar baseline characteristics during the time the 11 patients were voluntarily recruited into the study. Additionally, the Company released two key case studies of interest that demonstrated the potential clinical utility of Tollovir. All clinical results were collected by the Company's joint venture partner NLC Pharma in Israel. Dr. Ilan G. Ron, Clinical Professor of Oncology and Radiotherapy at Tel Aviv Medical Center Faculty & Medicine served as the Principal Investigator for the observational study.

"After decades of working to bring 3CL protease science to the forefront, we are disclosing the first initial clinical evidence of real-world benefit of our 3CL protease inhibitor drug candidate Tollovir® in a hospitalized patient setting," said Dr. Dorit Arad, Founder & Chief Scientific Officer of NLC Pharma. "We are extremely encouraged by these results, and this is really what pushed us to collaborate with Todos on bringing this potentially game-changing treatment forward in double-blind controlled clinical studies, which are currently in progress."

Results showed zero deaths in the Tollovir-treated group versus 5 deaths in the observed group. The mean age was slightly higher in the Tollovir group. The biomarker C-Reactive Protein (CRP) was measured upon hospitalization and tallied the number of patients that were able to experience a 50% reduction in this inflammatory biomarker within 48 – 72 hours. In the Tollovir group, 50% of the patients experienced a reduction of 50% or more in CRP versus only 10% in the observed group. Tollovir appeared to be well tolerated and showed only minor incidences of diarrhea which is consistent with the disease.

	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%)

Two case studies being released today which represent real-world use of the ingredients comprising Tollovir also showed successful outcomes after repeated failure from the Standard of Care treatment, including the EUA approved oral antiviral, Remdesivir.

Case Study #1

The patient was so severe that they were considering ECMO because her CRP was at 120 and her oxygen saturation was at 85%. This patient was given Tollovir, and stabilization in oxygen saturation at 98% was observed just 12 hours after treatment. The next day the CRP levels fell to 65, four days later her levels measured at 15, and eventually returned to normal shortly thereafter. She left the hospital 8-9 days after receiving Tollovir. This highlights the potential immunomodulatory properties of Tollovir that warrant further investigation.

Case Study #2

The patient had 3 comorbidities: ischemic heart disease, hypertension, and obesity. Despite treatment with antibiotics and steroids, his condition continued to deteriorate to the point of requiring hospitalization. He refused hospitalization and was offered the ingredients comprising Tollovir along with vitamins. Within 48 – 72 hours he reported improvement. Within 4 days the shortness of breath and cough almost completely disappeared.

“Based on these trial results, there appear to be very strong efficacy signals for Tollovir in treating hospitalized COVID-19 patients,” said Gerald Commissioning President & CEO of Todos Medical. “As we move forward in our clinical development program we expect Tollovir to do well in the upcoming rigorous placebo-controlled studies that are starting very soon at Shaare Zedek in Jerusalem. We are aggressively planning our expansion into new sites in Israel in order to accelerate enrollment because we believe that both the data generated in hospitalized patients and the observational study will support Emergency Use Authorization (EUA) applications in various jurisdictions. The reduction in mean hospitalization in our trial also shows that our planned next generation formula of Tollovir could have a significant impact on flattening the curve. These groundbreaking results are hypothesis generating and lend credence to our thesis about the Mechanism of Action (MOA) of Tollovir and its ability to treat a wide range of patients during the entire pathogenesis of COVID-19.”

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 2020, 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.

Todos Corporate and Investor Contact:

Richard Galterio

Todos Medical

732-642-7770

rich.g@todosmedical.com



Source: Todos Medical Ltd.