

August 11, 2022



# Todos Medical Completes Trial Design for Tollovid™ Long COVID Clinical Study in Adults

§ *3-arm randomized, controlled study to evaluate 15-day and 30-day treatment regimens*

§ *Finalizing contracts with two Long COVID clinics to recruit patients*

§ *Institutional Review Board (IRB) protocol submission imminent*

New York, NY, and Tel Aviv, ISRAEL, Aug. 11, 2022 (GLOBE NEWSWIRE) -- [via NewMediaWire](#) -- **Todos Medical, Ltd. (OTCQB: TOMDF)**, a comprehensive medical diagnostics and related solutions company, today announced that its majority-owned subsidiary 3CL Pharma, Ltd has finalized plans for a proposed safety and efficacy clinical trial for its 3CL protease inhibitor immune support dietary supplement Tollovid™ in patients with Long COVID. The 45-patient Part A of the study will be conducted as a 3-arm, randomized, controlled, observer-blinded clinical study evaluating Tollovid's effects on the structure/function of the immune system as measured by the presence of neutralizing antibodies, total anti SARS-CoV-2 antibodies (IgG, IgA, IgM) and VEGF cytokine levels.

Participating subjects will be randomized into three cohorts: 1) a 15-patient cohort to receive 30-day treatment regimen of 12 capsules per day; 2) a 15-patient cohort to receive a 15-day treatment regimen of 12 capsules per day, followed by 15-day treatment regimen of 6 capsules per day; and 3) an untreated control group who will be eligible to receive Tollovid at the conclusion study. All three groups will be allowed to continue taking their standard of care medications while on study, with the exception of other 3CL protease inhibitors. 3CL Pharma intends to initiate this clinical study in early fourth quarter of 2022. Two Long COVID clinics are in the process of finalizing contracts to participate in the study. It is the intention that study participants can enroll and be evaluated both virtually via remote monitoring, as well as in person.

The primary endpoints of Part A of the study are the numbers and severity of adverse events, serious adverse events (SAEs), clinical laboratory abnormalities and changes in vital signs after administration of Tollovid at day 30 following enrollment. The secondary structure/function endpoints of Part A of the study are changes in the Amerimmune/Provista Long Covid Panel, CRP and VEGF after administration of Tollovid at day 30 following enrollment. The exploratory objectives of Part A of the study are to evaluate time to improvement over time in the Post-COVID-19 Functional Status Scale scores and in COVID-19 symptoms after administration of Tollovid at day 30 after enrollment. Biomarker data will be gathered at baseline upon enrollment prior to treatment, midway through the study and at the conclusion of the 30-day treatment regimen for all three groups. The Company expects Part A of the study to complete in the fourth quarter of 2022.

If successful, a Part B of the study will be opened to rapidly expand patient enrollment, and potentially extend into pediatric patients, with a yet to be determined clinical design based upon the results of Part A and discussions with regulatory agencies.

“After gathering data from 3CL’s IRB-waived market research study of Tollovid, as well as numerous case studies, we have now settled on what we believe is the most pragmatic approach to get controlled clinical data for this commercially available dietary supplement. The knowledge gained should allow us to answer key clinical questions about its safety and efficacy in Long COVID,” said Dr. Dorit Arad, Co-Founder and Chief Technology Officer at 3CL Pharma. “Over the past few months, we have gathered a substantial body of anecdotal reports about Tollovid in both acute and Long COVID, however it is crucial that we understand its effect in a controlled trial setting so that we can communicate with consumers in the marketplace, as well as regulatory authorities with regard to Tollovid’s potential in Long COVID.”

### **About Tollovid™ and Tollovid Daily™**

Tollovid and Tollovid Daily are oral dietary supplement products made from natural ingredients that help support and maintain healthy immune function and also have potent 3CL protease inhibition properties based upon *in vitro* functional assays that show strong inhibition of 3CL protease activity. Tollovid and Tollovid Daily bind to the active site of the 3CL protease. Tollovid has a 5-day dosing regimen, with 4 doses of 3 pills taken each day that provides maximum immune support. Tollovid Daily is a daily immune support product with a dosing regimen of twice daily. Preliminary data from an ongoing IRB-waived study of customers who used the products to assist with their COVID and Long COVID were recently announced.

To purchase Tollovid please visit [Amazon](#) or [www.MyTollovid.com](http://www.MyTollovid.com).

### **About Tollovir™**

Tollovir is an oral 3CL protease inhibitor and anti-cytokine therapeutic candidate targeting the Nidovirus group of viruses that includes coronaviruses such as SARS-CoV-2, COVID-19, SARS-CoV-1, MERS and 229E. Tollovir is made from all natural ingredients that are qualified to ensure strong inhibition of the 3CL protease *in vitro*, as well as strong anti-cytokine activity. Tollovir has successfully completed a Phase 2 clinical trial in Israel for the treatment of patients hospitalized with COVID-19. Tollovir will be developed for the treatment of hospitalized COVID-19 (severe and critical), moderate COVID-19, Long COVID and, potentially, pediatric 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. 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 examines 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 acquired 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, [Long COVID Panel](#) analyses, and Provista's proprietary commercial-stage Videssa® breast cancer blood test. More information on Provista is available at [www.provistadx.com](http://www.provistadx.com).

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 formed the Israeli-based majority-owned joint venture 3CL Pharma, Ltd with NLC Pharma in March of 2022 to consolidate all of the intellectual property surrounding 3CL protease-based diagnostic testing and development of 3CL protease botanical and pharmaceutical inhibitors that target a fundamental reproductive mechanism of coronaviruses. 3CL Pharma, through Todos' brand, has commercialized the 3CL protease inhibitor immune support dietary supplement Tollovid™ in the United States, is developing the dual mechanism 3CL protease inhibitor and anti-cytokine therapeutic drug candidate Tollovir™, while also developing the 3CL protease diagnostic TolloTest™.

To purchase Tollovid please visit [Amazon](#) or [www.MyTollovid.com](http://www.MyTollovid.com). 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 the 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 Contact:**

Daniel Hirsch

CFO

Todos Medical

917-983-4229 x 104

Dan.h@todosmedical.com



Source: Todos Medical Ltd.