October 6, 2021

Todos Medical Announces Positive Data in Hospitalized and Outpatient Setting for TolloTest™, a Novel SARS-CoV-2 3CL Protease Biomarker Assay

Data demonstrated very high correlation with PCR ct values in positive patients

Data demonstrated 100% sensitivity, as early as 1-3 days post-exposure, in identifying fully vaccinated asymptomatic patients infected with COVID-19

New York, NY, and Tel Aviv, ISRAEL, Oct. 06, 2021 (GLOBE NEWSWIRE) -- via NewMediaWire -- **Todos Medical, Ltd. ("Todos Medical") (OTCQB: TOMDF)** a comprehensive medical diagnostics and related solutions company, together with its joint venture partner NLC Pharma, today announced positive clinical validation data for its 3CL protease biomarker assay TolloTest™ in a clinical study evaluating its sensitivity compared with PCR in hospitalized COVID-19 patients, patients hospitalized for conditions other than COVID-19 and individuals exposed to confirmed COVID-19 subjects in the community outpatient setting and healthy controls. The results clinically validated the sensitivity of the 3CL protease biomarker compared with SARS-CoV-2 PCR confirmed positive results in both the hospital and outpatient setting, and provided key insights on the potential role the 3CL protease biomarker could play in assessing the COVID infectivity status of infected patients being released from quarantine and opening the diagnostic window to include earlier diagnosis of individuals from time of time known exposure. The Company sees multiple use cases for the 3CL protease biomarker as an adjunct to both PCR testing and antigen testing for SARS-CoV-2.

The 3CL protease is the main protease found in coronaviruses. When a cell becomes infected with the virus, one of the first viral components made is the 3CL protease, which is an enzymatic saw that cleaves coronavirus polypeptides into usable viral proteins. Since a healthy human body doesn't contain any traces of 3CL protease it's an ideal biomarker that will show up only if there is active infection. In theory a 3CL protease test is a much better test for pandemic management because it could identify patients who are capable of spreading the disease and help them.

"We believe that the 3CL protease could become a very important biomarker in the overall COVID-19 diagnostic landscape," said Jorge Leon, PhD, Chief Scientific Officer at Todos Medical. "To date, the only questions that the widely used PCR and antigen testing tools can answer is whether or not a person has certain fragments of the SARS-CoV-2 virus in their system, not whether that virus is actively replicating and can be spread to others. Neither PCR or antigen tests have the ability to measure infectivity. As we move forward in dealing

with this deadly pandemic, key questions about whether an infected person, or someone who continues to test positive by PCR for weeks/months despite recovery from viral infection, is actively infectious are becoming increasingly important if we want to control community spread. We believe a potential solution to address this question is the 3CL protease biomarker. Additionally, it appears the 3CL protease biomarker assay may open the diagnostic window to more accurately reflect the initial presence of SARS-CoV-2, as well as a more accurate measure of when a person is no longer infectious post-diagnosis than mandatory 7-, 10- or 14-day quarantine measures. The length of quarantine should be driven by infectivity biomarkers, not by relatively arbitrary estimates of how long infectivity may last."

The initial format of the TolloTest assay is immunofluorescence. The TolloTest lab assay performance has been optimized for use with nasal mid-turbinate (NMT) collected samples, consistent with the most widely used specimen collection protocols, with fluorescent reaction occurring within 10 minutes of the sample being applied into the assay. The result yields a quantitative assessment of the activity of 3CL protease, which is highly consistent with PCR cycle time values (ct values). Based upon the data generated, the Company is confident that it can optimize TolloTest for various point-of-care (POC) assay formats that would allow for ease of use similar to current rapid COVID tests, including a qualitative lateral flow assay format that could be used as an adjunct to currently available antigen tests to improve their sensitivity for earlier diagnosis, asymptomatic screening, and release from quarantine, or a quantitative POC test that could provide a non-lab test based tool to monitor the level of viral infection, providing data that mirrors PCR ct values. At-home testing formats are also possible.

In the first part of the clinical study, 58 hospitalized patients and research staff were recruited and evaluated for SARS-CoV-2 infection as measured by PCR, with 30 negative subjects and 28 positive patients enrolled being treated for COVID-19. Of the 30 subjects who tested negative by PCR, 12 were in a subgroup determined to be positive by TolloTest. These 12 individuals may have had SARS-CoV-2 exposure or may have been infected with another coronavirus such as a common cold (HCoV-229E). Of the 28 hospitalized patients who tested positive by PCR, 25 tested positive by TolloTest. Of the 3 PCR positive patients who tested negative by TolloTest, all three had PCR cycle time values (ct values) of 30 of higher, indicating they were likely nearing or at the end of their viral disease process and were likely no longer infectious. As expected, there was a consistent inverse correlation between ct value and 3CL protease activity in both hospitalized and non-hospitalized subjects.

A table of the hospitalized patient set is available below:

	PCR Negative	PCR Positive
3CL Positive	**12**	**25**
3CL Negative	**18**	**3**
N=58	**30**	**28**
Sensitivity (TP)	**0.89**	
Sensitivity (TN)	**0.60**	

Of key interest in the hospitalized patient setting is the fact that 7 of the 25 PCR confirmed positive patients who also tested positive by TolloTest were discharged within 48h of testing positive by TolloTest, indicating patients may have been discharged who still harbored residual active virus even after resolution of their clinical symptoms. This group of potentially

infectious people being released to their homes post-quarantine highlights a key failing with the current testing paradigm. Community spread is facilitated when infectious people are cleared back into the community before the actively replicating virus has been fully cleared from the patient.

Following completion of the data gathered in the hospital setting, the Company was able to recruit an additional 17 subjects, all fully vaccinated, into the study from a community event setting held from July 12-17, 2021 in Israel. All 17 enrolled individuals attending the event were notified of close exposure to a known positive COVID-19 patient, with some patients becoming symptomatic several days post-exposure. Beginning on July 15th, 2021 and ending on July 27th, 2021, all 17 patients were enrolled into the study. Of the 17 patients enrolled, 16 were positive by PCR and 1 was negative by PCR. Of the 16 positive patients, TolloTest identified all 16 as being COVID-19 positive and identified the only negative subject as negative. In this very small group of patients the TolloTest performed flawlessly, with a perfect score of 100% sensitivity and 100% specificity.

A table of the COVID-19 community outbreak data is available below:

	PCR Negative	PCR Positive
3CL Positive	**0**	**16**
3CL Negative	**1**	**0**
N=17	**1**	**16**
Sensitivity (TP)	**1.00**	
Sensitivity (TN)	**1.00**	

Todos now intends to evaluate various assay formats to optimize ease of use in the POC setting and turnaround times in the lab setting to address these multiple use cases. The company plans on conducting additional confirmatory studies with the final, optimized POC assay formats with the goal of eventually submitting for an EUA. The Company is in active discussion with potential partners with POC products on the market to help accelerate bringing this critically important biomarker on to the market.

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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Source: Todos Medical Ltd.