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Todos Medical Announces Positive Proof-of-Concept Data for Novel 10-Minute Point-of-Care Saliva-based Test Detecting Active SARS-CoV-2 Infection

- *Achieves analytical performance for detecting active 3C-protease in a rapid visual format*
- *Initiates multicenter clinical trial at Assuta Ashdod Hospital and Tel Aviv University in Israel*
- *Technology opens potential for self-administered tests at home, school, work and airports*

NEW YORK, NY REHOVOT, Israel, and SINGAPORE, Aug. 17, 2020 (GLOBE NEWSWIRE) -- via NEWMEDIAWIRE -- Todos Medical Ltd. (OTCQB: TOMDF), an *in vitro* diagnostics company focused on distributing comprehensive solutions for COVID-19 screening and diagnosis, and developing blood tests for the early detection of cancer and Alzheimer's disease, today announced positive proof-of-concept data for its proprietary 10-minute rapid point-of-care saliva-based test for detecting active SARS-CoV-2 infections. Based on these data, the Company has initiated a multicenter clinical trial at Assuta Ashdod Hospital and Tel Aviv University in Israel to evaluate the clinical performance of the assay, and optimize product development prototypes for commercial scale-up.

This technology holds promise to provide a rapid result without the need for heating, expensive instrumentation, inconvenient sample collection or cold-chain logistics. As such, it may have applicability for self-testing at home, or where large numbers of people gather such as school, work, airports, etc. Todos envisions developing both quantitative and qualitative tests based on the technology and intellectual property. The Company is working to complete this initial clinical trial in the third quarter of 2020, with trial results and submissions to regulatory agencies worldwide in the fourth quarter of 2020.

"These data provide proof-of-concept for the 3C-Protease diagnostic approach in COVID-19 testing," said Dr. Jorge Leon, consulting Chief Medical & Scientific Officer of Oncology and Infectious Disease for Todos. "The clinical trial in Israel will generate real-world data on how best to integrate this technology platform into products that can be deployed worldwide. We will now begin incorporating the software to analyze this assay into an application for use with mobile phones and various telemedicine platforms, so as to provide a more complete and efficient solution for COVID-19 testing and data reporting for all stakeholders."

The proof-of-concept analytical performance data demonstrate that the assay is able to accurately detect the SARS-CoV-2 3C-Protease in human saliva samples spiked with recombinant 3C protease, and that the protease signal was specifically and significantly distinguishable from background protease activity present in normal saliva. The 3C-Protease is a coronavirus-derived protein that is required for viral replication and transmission to other cells and tissues. The 3C-Protease assay detects the presence of *active* viral replication specific to SARS-CoV-2, rather than host reactions to current or previous other coronavirus infections, or the detection of viral genetic fragments that continue to shed from patients who have recovered from COVID-19. As more people become infected and recover from COVID-19 worldwide, it is becoming increasingly important for a molecular assay to distinguish active, replicating SARS-CoV-2 virus from inactive, non-replicating SARS-CoV-2 genetic fragments.

Data on the importance of the 3C-Protease in coronaviruses was recently published in *Science Translational Medicine*, available [here](#). Patents covering the use of the 3C-Protease for the detection of the SARS-CoV-2 were filed in the first quarter in of 2020 by Todos' joint venture partner NLC Pharma. The joint venture, named COVID Antigen Test Killer (CATK), is focused on the development of molecular diagnostic tests that are differentiated from currently available tests to enable point-of-care detection of the virus in its reproduction stage in minutes, as well as quantitative analysis of how quickly the virus is replicating, which is a measure of viral load. Assay data would give healthcare providers more meaningful information with which to triage patients with COVID-19.

"We are extremely pleased to have confirmed the usefulness of our 3C-Protease patented viral detection technology for COVID-19," said Dr. Dorit Arad, Chief Scientific Officer of NLC Pharma. "With these data in hand, we see a clear path to apply our technology at large scale to provide widespread rapid, highly-sensitive molecular testing to make a difference in the rapid detection of active COVID-19. We believe this sets the stage for significant growth within our joint venture with Todos."

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.

Headquartered in Rehovot, Israel, 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 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. In July 2020, Todos completed the acquired Breakthrough Diagnostics, Inc., the owner of the LymPro Test intellectual property, from Amarantus Bioscience Holdings, Inc. (OTC: AMBS).

Additionally, 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 strategic partnerships with [Meridian Health](#), [Moto-Para Foundation](#) to deploy COVID-19 testing in the United States.

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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