Todos Medical’s CLIA/CAP Lab Provista Completes Validation of High-Capacity SARS-CoV-2 Variant Testing Service Capable of Identifying Known Variants

- Company sees a significant market opportunity for reference lab agreements to identify which variant is responsible for positive COVID-19 test results
- Validation paves the way for launch of variant testing at Provista in September 2021

New York, NY, and Tel Aviv, ISRAEL, Aug. 26, 2021 (GLOBE NEWSWIRE) -- via NewMediaWire -- Todos Medical, Ltd. (OTCQB: TOMDF), a comprehensive medical diagnostics and related solutions company, today announced that its CLIA/CAP certified lab Provista Diagnostics has successfully completed the validation studies required to put the Kogene Biotech PCR Variant Test Kit (‘Kogene Variant Kit’) into production and expects to launch variant testing in September 2021. The Kogene Variant Kit is a PCR kit capable of identifying the key mutations associated with specific SARS-CoV-2 variants, including the key P681R mutation identified in the Delta variant, that allows Todos to categorize the lineage of the strain responsible for a positive test result. The test can be completed in as little as one hour, significantly faster than genome sequencing, and is highly scalable with the Tecan® liquid handling automation currently onsite at Provista.

“With the rising number of breakthrough infections caused by the Delta variant that now represents approximately 96% of cases, up from 3% in early July 2021, it has become extremely clear that the United States’ genomic sequencing capabilities are unable to keep up with the sheer volume of demand for classifying which variants are responsible for SARS-CoV-2 infections,” said Gerald E. Commissiong, President & CEO of Todos Medical. “Not only is there significant public health interest in tracking variants, there is also an emerging clinical difference in how physicians may speed the prescription of certain treatments based upon which variant a patient has. This clinical utility, initially seen with the Alpha variant and now more pronounced with the Delta variant, means that we must prepare for the future where we expect new variants, such as the Lambda variant, that appear more capable of escaping vaccination protection and may result in more aggressive treatment strategies. The ability for Provista to scale this test offering rapidly with our automation by reflexing positives for variant analysis and by expanding our reference lab network to confirm which variants are responsible for other labs’ positive results will improve regional understanding of the spread of new variants as they emerge, and provide schools, businesses, and public health officials an ability to react more quickly with policy changes.”
Todos sees a large market opportunity developing for variant testing that will further expand upon the COVID-19 PCR testing market that rapidly developed into an $80 billion market worldwide in 2020. Provista Diagnostics has the automation in place to do up to 20,000 PCR tests, over 1,500 cPass tests per day and can complete over 5,000 variant tests per day when at full capacity. The CMS reimbursement rate per PCR test is $100, and best practices indicate that labs can bill for an additional PCR test to confirm the variant associated with a positive when using the Kogene Variant Kit. To date, over 37 million people in the United States have tested positive for COVID-19, and with the rate of breakthrough infections rapidly increasing, tracking variants of interest and of concern is now urgently needed.

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 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 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 and Provista's proprietary commercial-stage Videssa® breast cancer blood test.

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 has entered into distribution agreements with companies to distribute certain (COVID-19) testing materials and supplies. The agreements cover multiple suppliers of PCR testing kits, extraction kits, automation materials and supplies, as well as COVID-19 antibody and antigen testing kits.

Todos has entered into a joint venture with NLC Pharma to pursue the development of diagnostic tests targeting the 3CL protease, as well as 3CL protease inhibitors that target a fundamental reproductive mechanism of coronaviruses.

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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