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ASX Announcement
TBG Biotechnology Corp. Confirms CE Mark approval of COVID-19 Nucleic Acid and Antibody Rapid Test Kits

TBG Diagnostics Limited ("TDL" or "Company") is pleased to announce that its wholly owned subsidiary TBG Biotechnology Corp. ("TBG Taiwan") has received the CE Mark approval for its ExProbe™ SARS-CoV-2 Testing Kit and SARS-CoV-2 IgG / IgM Rapid Test Kit.

CE Mark certification indicates that the ExProbe™ SARS-CoV-2 Testing Kit and SARS-CoV-2 IgG / IgM Rapid Test Kit meet the essential health, safety, and environmental protection requirements of the applicable European regulations to allow the sale of the kit throughout the European Economic Area as well as any country that accepts CE-mark, subject to satisfying regulatory requirements and obtaining import permits for individual countries. Both tests are manufactured by TBG Biotechnology Corp. in Taiwan and will be exported from Taiwan subject to meeting the regulatory requirements of the destination country.

The ExProbe™ SARS-CoV-2 Testing Kit is a RNA based diagnostic kit that uses real time PCR technology with multiplex design to detect distinctive segments within RdRP, N and E genes of the SARS-CoV-2 virus in a single reaction. It is commonly used to confirm active infection of the SARS-CoV-2 virus.

The SARS-CoV-2 IgG / IgM Rapid Test Kit test is a lateral flow assay that is able to detect IgG and IgM antibodies against specific protein epitopes on the N and S proteins of the SARS-CoV-2.

The Company expects the test to take 15 minutes to complete and detect the presence of SARS-CoV-2 specific IgM and IgG antibodies in the blood, serum and plasma. IgM and IgG antibodies usually generated in the body 7-10 days after SARS-CoV-2 infection and can last for weeks. This test is often used to confirm if he/she has been infected with the COVID-19 virus. This rapid test uses droplet of blood, serum or plasma as testing sample. Together, these two test products are expected to be able to confirm symptomatic individuals with an active SARS-CoV-2 viral infection and those who have been infected by SARS-CoV-2 and generated a specific antibody response.

Authorised by the Board of Directors
Jitto Arulampalam
Chairman