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ASX Announcement

TBG Biotechnology Corp. Receives US FDA Emergency Use Authorisation (EUA) for its COVID-19 Nucleic Acid Test Kits

TBG Diagnostics Limited ("TDL" or "Company") is pleased to announce that its wholly owned subsidiary TBG Biotechnology Corp. ("TBG Taiwan") has received an Emergency Use Authorisation (EUA) from the United States Food and Drug Administration (FDA) for its ExProbe™ SARS-CoV-2 Testing Kit.

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 from a specified range of upper and lower respiratory samples. This test is manufactured by TBG Biotechnology Corp. in Taiwan and will be exported from Taiwan.

The United States FDA has made the Testing Kit available under an emergency access mechanism called an EUA. The EUA is supported by the Secretary of Health and Human Service's declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19. Since the Testing Kit is made available under an EUA, it has not undergone the same type of review as an FDA-approved or cleared IVD.

The EUA for the Testing Kit is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

Under the EUA, the ExProbe SARS-CoV-2 Testing Kit is only authorised for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

The FDA concluded that the Testing Kit met the criteria for issuance of the EUA which are listed in Section I on page 2 of the Letter of Authorization. A full copy of the Letter of Authorization from the FDA, which includes the conditions attached to the EUA, is available on the FDA website at https://www.fda.gov/media/138819/download.

The Fact Sheets for Healthcare Providers and Patients for the Testing Kit and the Instructions for Use are also available from the FDA website at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd.

The Testing Kit is one of 100 in vitro diagnostics test kits for detection and/or diagnosis of the novel coronavirus which have received FDA EUAs to date.

Authorised by the Board of Directors
Jitto Arulampalam
Chairman