ASX Announcement **28 June 2021**

Access Bio receives FDA clearance for COVID-19 antibody test

SYDNEY Australia Monday, 28 June 2021: Atomo Diagnostics Limited (ASX: AT1) (**Atomo**) is pleased to advise that Access Bio Inc. (KOSDAQ: 950130) (**Access Bio**) has received Emergency Use Authorisation (**EUA**) from the U.S. Food and Drug Administration (**FDA**) for point-of-care use of its CareStart™ EZ COVID-19 IgM/IgG test. Access Bio's announcement to the Korea Exchange is attached.

CareStart™ EZ COVID-19 IgM/IgG is a rapid antibody test made by combining an integrated device developed by Atomo and a rapid COVID-19 antibody test strip from Access Bio.

Atomo announced on 28 July 2020 that it had entered into an agreement to supply Access Bio with its unique, integrated rapid diagnostic test (**RDT**) devices for use in North America with Access Bio's rapid test strip for detection of antibodies to COVID-19 subject to FDA clearance. Atomo thereafter announced, on 29 September 2020, the expansion of this rapid test partnership to grant Atomo non-exclusive rights to market and distribute Access Bio's COVID-19 rapid antigen test in Australia, New Zealand and India, subject to obtaining the required regulatory approvals in each jurisdiction.

This EUA allows sales of the CareStart™ EZ COVID-19 IgM/IgG test for use in point-of-care settings like doctors' offices, hospitals and emergency rooms in the United States.

Atomo and Access Bio are in discussions regarding their COVID-19 rapid test commercial arrangements and Atomo will keep the market informed as to any material developments.

Atomo's Managing Director John Kelly said, "We are happy that our integrated test device has enabled Access Bio to secure EUA for point-of-care use for their COVID19 antibody test and for it to be used in a broad range of non-laboratory settings in the US."

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This announcement was authorised by John Kelly, Managing Director.

About Atomo
Atomo is an Australian medical device company supplying unique, integrated rapid diagnostic test (RDT) devices to the global diagnostic market. Atomo's patented devices simplify testing procedures and enhance usability for professional users and untrained self-testers. Atomo has supply agreements in place for tests targeting a range of infectious diseases including for HIV, COVID-19, and viral vs bacterial differentiation.
See more at www.atomodiagnostics.com.

Access Bio Receives Emergency Use Authorization by US FDA for COVID-19 Antibody Test Kit

[Seoul, South Korea – June 25, 2021]

Access Bio announced the U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for its *CareStart*™ EZ COVID-19 IgM/IgG for point-of-care use.

CareStart™ EZ COVID-19 IgM/IgG is a rapid test made by combining an integrated device developed by Atomo Diagnostics and a rapid COVID-19 Antibody test strip from Access Bio.

CareStart™ EZ COVID-19 IgM/IgG is an immunochromatographic lateral flow assay intended for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in fingerstick whole blood. This rapid test is intended for use an aid in identifying individuals with an adaptive immune response to SARS-COV-2, indicating recent or prior infection.

In addition, as the accessories necessary for diagnosis are integrated directly into the device, usability has been simplified and the convenience of diagnosis has been greatly improved. In the clinical trial conducted for this emergency use authorization sensitivity was recorded at 97% and 100% for IgG and IgM, respectively, delivering 100% specificity for both IgG and IgM, demonstrating excellent performance.

This improved usability in professional use settings has enabled the test to secure EUA for point-of-care use making it one of only a small number of rapid COVID-19 Antibody tests authorized by US FDA.

“As vaccinations are accelerating, the demand to check whether or not antibodies are produced is only increasing. Our rapid tests will be useful in doctor’s offices and clinics in pharmacies with good accessibility.” said Young Ho Choi, CEO of Access Bio. “As the possibility of a third vaccination is emerging as a prediction of the re-spreading of the coronavirus this fall, we expect that the antibody diagnosis will help in the determination of the need for a further booster vaccination.”

Atomo’s Managing Director John Kelly said, “We are happy that our integrated test device has enabled Access Bio to secure EUA for point-of-care use for the test and for it to be used in a broad range of non-laboratory settings in the United States, and we look forward to expanding our partnership with Access Bio to include other jointly developed tests in the coming years”.

Meanwhile, Access Bio is in the progress of EUA for the COVID-19 antigen self-test kit in the United States. This COVID-19 antigen self-test kit can diagnose various variants of COVID-19, including the delta variant from India, the beta variant from South Africa, and the alpha variant from the UK, which are highly transmissible and possibly more dangerous than current predominant COVID-19 virus.