ASX Announcement **29 September 2020**

Atomo and Access Bio expand partnership to launch a rapid COVID-19 antigen test in Australia, NZ and India

Highlights:

- **Atomo has the non-exclusive rights to market Access' COVID-19 rapid antigen test in Australia, New Zealand and India under an Atomo brand, the Atomo COVID-19 Antigen Test**
- **Access Bio's rapid antigen test is already CE Marked for professional use in Europe and an Emergency Use Authorization (EUA) from the US FDA is currently pending**
- **Combined antigen / antibody testing at the point of care has the potential to be significant in the diagnosis and treatment of COVID-19**

SYDNEY Australia, Tuesday, 29 September 2020 – Atomo Diagnostics Limited (ASX: AT1) (**Atomo**) is pleased to announce it has expanded its existing COVID-19 rapid test partnership with Access Bio LLC, (**Access**), previously announced to ASX on 28 July 2020.

Under the expanded partnership, Atomo will have non-exclusive rights to market and distribute Access' COVID-19 rapid antigen test in Australia, New Zealand and India, branded the Atomo COVID-19 Antigen Test, subject to obtaining the required regulatory approvals in each jurisdiction.

The Atomo COVID-19 rapid antigen test is a nasopharyngeal swab test designed to screen for antigens produced in response to COVID-19 infections at the point of testing and a positive result implies current viral infection[1]. Unlike the general nasal swab testing in Australia which typically uses molecular PCR assays to test for the presence of the virus and must go to a central laboratory for processing, the Atomo COVID-19 Antigen Test is processed at the point of care and results are available after 10 minutes. As such, antigen testing may have benefits

[1] Centre for Disease Control (2020), *Interim Guidance for Rapid Antigen Testing for SARS-CoV-2,* https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html (last accessed on 28 September 2020).

for early identification and controlling outbreaks in some situations, compared to PCR tests in settings with prolonged turnaround times' [2]

The rapid antigen test has the potential to complement Atomo's TGA approved AtomoRapid COVID-19 rapid antibody test, which identifies whether a patient has developed antibodies to the virus and is most accurate around 15 days from exposure. In comparison, the Atomo COVID-19 Antigen Test is most accurate immediately after the onset of symptoms. By running the two tests in parallel, patients would understand within 15 minutes, with a high degree of accuracy, whether they currently have COVID-19, or whether they may have had it previously. Atomo will purchase finished product from Access at a fixed price per unit and considers that, if it is successful in obtaining regulatory approvals in Australia, New Zealand and India, the potential revenue and earnings generated will be material.

Atomo's co-founder and Managing Director, John Kelly, said, "*Atomo is delighted to have secured rights to market a quality US manufactured rapid antigen test from a trusted partner. We believe that having the ability to screen for both acute infection and prior exposure at the same time, with results delivered after 10 minutes at the point of testing, could be game-changing in the way we diagnose COVID-19.*

Mr Kelly added that, *"Antigen tests have been proven to provide good detection of COVID-19 infection in the early stage onset of symptoms. Combined with our TGA-approved rapid antibody test for COVID-19 that reliably detects exposure to the virus over a longer period, we believe that a combo rapid screen will offer excellent performance outside of laboratory settings where reliable testing is most needed."*

Access will remain the listed manufacturer of the test with Atomo acting as a product sponsor, responsible for registering the product in each jurisdiction under the Atomo brand. The test is already CE Marked for professional use in Europe and an EUA from the US FDA is currently pending. Based on a third party clinical evaluation sponsored by Access which tested a total of 126 samples [43 positive and 63 negative nasopharyngeal swab specimens, and 20 contrived near the cut-off (10 positive and 10 negative) swab specimens] collected from patients in the US with COVID-19 onset symptoms, and submitted to the FDA and used to support CE Mark, the Access COVID-19 antigen test demonstrated Sensitivity of 88.4% and Specificity of 100%.

[2] Centre for Disease Control (2020), Interim Guidance for Rapid Antigen Testing for SARS-CoV-2, https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html (last accessed on 28 September 2020).

For more information, please contact:

Jane Lowe
IR Department
jane.lowe@irdepartment.com.au
Phone: +61 411 117 774

John Kelly
Atomo Diagnostics Limited
john.kelly@atomodiagnostics.com
Phone: +61 401 922 279

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. The Company has supply agreements in place for tests targeting infectious diseases including COVID-19, HIV and viral vs bacterial differentiation.
See more at www.atomodiagnostics.com.

About Access Bio

Headquartered in Somerset, New Jersey, and listed on the Korean Stock Exchange (KOSDAQ: 950130),Access Bio is a specialist biotechnology company dedicated to the prevention and early diagnosis of infectious diseases through research, development, and manufacturing of in vitro rapid diagnostic tests, biosensor, and molecular diagnostic products. With established manufacturing facilities in the USA, South Korea and Ethiopia, Access Bio and its subsidiaries manufacture more than 120 million rapid diagnostic tests annually for the detection of a range of diseases, including malaria, dengue, HIV and now COVID-19.
See more at www.accessbio.net