ASX Announcement **10 August 2020**

Atomo receives TGA approval for its COVID-19 rapid antibody test

- Australian Therapeutic Goods Administration (TGA) has approved the AtomoRapid™ COVID-19 (IgG/IgM) test for inclusion on the ARTG for supply to departments of health, laboratories, medical practitioners and health care professionals in residential and aged care facilities
- The test can determine if a patient has developed antibodies to the COVID-19 virus, with results obtained from a drop of blood within 15 minutes
- Commercial channels now being pursued include public health providers, corporate OH&S, aged care and other large institutions

SYDNEY Australia Monday, 10 August 2020: Atomo Diagnostics Limited (ASX: AT1) (**Atomo**) is pleased to announce that the Therapeutic Goods Administration (**TGA**) has approved its rapid SARS-CoV-2 antibody blood test for use by medical professionals in Australia. For further information on the Atomo test, refer to Atomo's announcement on 4 June 2020.

With approval now granted for the AtomoRapid™ COVID-19 (IgG/IgM) test, the product will now be added to Atomo's existing Australian Register of Therapeutic Goods (**ARTG**) listing, alongside the Atomo HIV Self-Test. This is a routine procedure which is expected to be completed shortly. Once listed, Atomo can commence supply of the test to departments of health, laboratories, medical practitioners and health care professionals in aged care facilities in Australia.

The AtomoRapid™ COVID-19 (IgG/IgM) test is jointly manufactured by Atomo and NG Biotech in France, with NG Biotech manufacturing the test strip and Atomo manufacturing the device and being the listed manufacturer. The Atomo test approved by the TGA is the same as the test that is already approved and being sold by NG Biotech in France.

Atomo Diagnostics co-founder and Managing Director John Kelly said, "Thanks to the TGA approval and the work of our dedicated team, we can now deliver what is in our view, a high-

quality, reliable antibody rapid test to Australia." Mr Kelly added, "Atomo already sells Australia's only approved HIV Self-Test and we know that our solution simplifies rapid blood-based testing in point-of-care settings. We are excited that our test can now be used in our home market, Australia, to assist in the fight against the COVID-19 pandemic."

Test performance and safety evidence

A study of the COVID-19 test conducted in Atomo's Pascal device by Hopital Bicêtre, France which tested 256 sera from 101 patients hospitalised with SARS-CoV-2 infection (positive RT-PCR) for IgM and IgG found that "**Sensitivity and Specificity were 97.0% and 100% respectively**, 15 days after the onset of symptoms." The research was supported by Assistance Publique – Hôpitaux de Paris (APHP), Médecins Sans Frontières (MSF), and by a Grant from the French Defence Innovation Agency (AID).

A further study of the COVID-19 test conducted in Atomo's Galileo device at the Pasteur Institute, France, which tested 78 positive and 22 negative samples collected from patients who were confirmed positive or negative using the RT-PCR method for IgM and IgG, found that 15 days after the onset of symptoms **Sensitivity and Specificity were 96.8% and 100% respectively**.[1]

The TGA has approved the COVID-19 test on the Galileo device. The results of the two independent studies of the COVID-19 test on our Pascal and Galileo devices indicates materially equivalent results with both studies demonstrating 100% specificity.

Atomo notes that, as stated in its 4 June 2020 announcement, Dr Alan Finkel, Australia's Chief Scientist, provided a report to Federal Health Minister The Hon Greg Hunt MP entitled, 'The predictive value of serological testing during the COVID-19 pandemic' dated 30 April 2020 which concluded that: "For as long as the prevalence of COVID-19 is low in Australia and available serological tests are not approaching 100% specificity, serological testing to measure the prevalence of COVID-19 will not be meaningful. As noted earlier, the Atomo rapid test meets this requirement having demonstrated 100% specificity in both studies in France.

[1] *Pasteur Institute Report - Performance evaluation for the detection of SARS-CoV-2 antibodies, National Reference Center for Respiratory Infection Viruses (including influenza), Paris, France (Unpublished).*

The TGA requires all approved manufacturers and distributors of COVID-19 antibody test kits to provide it with additional evidence to demonstrate ongoing safety and performance within 12 months of approval.

The Peter Doherty Institute for Infection and Immunity (**Doherty Institute**) has been engaged by the Department of Health to assist with the post-market validation of new COVID-19 rapid tests to inform their best use. Atomo will look to submit the AtomoRapid™ COVID-19 (IgG/IgM) antibody test for assessment by the Doherty Institute now that it has been approved and is being listed on the ARTG for sale in Australia.

Commercial market opportunities

Atomo has had preliminary commercial discussions to assess distribution channels for its test within Australia. Now that TGA approval has been received, Atomo will further engage across segments where it believes COVID-19 antibody testing has a significant role to play. These segments include public health providers, corporate OH&S, aged care and other institutions. Any commercial relationships in Australia would add to Atomo's current revenue accretive supply agreements for COVID-19 testing with offshore partners, Access Bio (USA/Korea) and NG Biotech (France). With the majority of current production committed under existing contracts, an initial allocation of 100,000 units has been allocated to the Australian market, to be scaled up based on demand.

John Kelly commented, "We see strong potential for use of our test across a number of channels in Australia and we believe TGA approval will accelerate these negotiations. In our view, the performance data for the test generated from independent French studies and the proven ease-of-use of the Atomo device in the field, make our test well suited for deployment in a large country like Australia, with a variety of point of care settings."

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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.

About antibody testing

The AtomoRapid COVID-19 (IgG/IgM) is an integrated rapid blood test designed to determine if a patient has developed antibodies generated in the body in response to exposure to the COVID-19 virus. The test is run without the need for any instrumentation and results are obtained from a drop of blood within 15 minutes.

Antibody (or serology) tests can be used to determine if a person has previously been exposed to the COVID-19 virus and has developed an antibody response to the virus. An antibody response to an infectious virus is typically considered to indicate some potential level of immunity for a period of time, although in the case of COVID-19 this link is not yet characterised given its very recent arrival in humans.