ASX Announcement **4 June 2020**

Atomo and NG Biotech expand COVID-19 partnership: Atomo secures exclusive rights for Australia, New Zealand and South East Asia[1]

SYDNEY Australia, Thursday, 4 June 2020 – Atomo Diagnostics Limited (ASX: AT1) (**Atomo**) is pleased to announce it has expanded its existing COVID-19 rapid test partnership with NG Biotech, SAS (**NG Biotech**), which was announced to ASX on 14 April 2020 in Atomo's Second Supplementary Prospectus (**Second Supplementary Prospectus**).

Under Atomo's existing binding supply agreement with NG Biotech referenced in the Second Supplementary Prospectus, Atomo has been supplying NG Biotech with its award-winning Galileo rapid test device for use in NG Biotech's blood-based rapid antibody IgG/IgM COVID19 test (the **COVID-19 antibody test**) which is branded 'NG Test IgG / IgM COVID19' when sold by NG Biotech in Europe. To date, NG Biotech has ordered in excess of 1.5 million Galileo devices from Atomo for use in NG Biotech's COVID-19 antibody test in France.

Under the expansion of the Atomo NG Biotech partnership, Atomo now has exclusive rights to market and distribute, as the listed manufacturer, the COVID-19 antibody test in Australia and New Zealand and a number of countries in South East Asia[1], subject to obtaining the required regulatory approvals in each jurisdiction, under the brand 'AtomoRapid™ COVID-19 (IgG/IgM)'. At present, the period of exclusivity has not been specified (ie. it is not currently limited) and Atomo and NG Biotech are continuing to negotiate a definitive long term supply agreement. The pricing arrangements with NG Biotech are limited to a price payable per unit only and do not include any licence fees or royalties.

The exclusive rights arrangement for Australia, New Zealand and a number of South-East Asian countries is strategically important for Atomo as it repositions Atomo as a listed manufacturer of COVID-19 tests, building on its foundation of being the only manufacturer of

[1] Countries included in South East Asia are: Singapore, Malaysia, Indonesia, Taiwan, Hong Kong, Thailand, Vietnam, Myanmar and the Philippines.

[2] **Listed manufacturer** is a regulatory term that denotes the legally responsible manufacturer. The name of the listed manufacturer must be detailed on the product labelling. They hold the approval for the product and they are responsible for post market surveillance of the product.

a TGA approved Class 4 Self-Test in Australia, listed as the 'Atomo HIV Self-Test' on the ARTG.

In Atomo's opinion, if it is successful in obtaining the required regulatory approvals in each of the exclusive markets and securing commercial sales arrangements, the potential revenue and earnings generated will be material.

As CE Marking is an internationally recognised quality standard for medical devices, Atomo believes that approaching regulators in South-East Asia with the CE Marking of the AtomoRapid™ COVID-19 (IgG/IgM) test in place, is likely to assist with the regulatory process, particularly in Hong Kong, Taiwan and the Philippines. Atomo further believes that the regulatory requirements in each of the South-East Asian and New Zealand markets will be no more onerous than the CE Marking and TGA approval processes. All approvals sought by Atomo for the AtomoRapid™ COVID-19 (IgG/IgM) test will be limited to professional use only.

Atomo has made an application to the TGA for a Conformity Assessment Certificate for the AtomoRapid™ COVID-19 (IgG/IgM) test. The approval sought is limited to professional use only, and subject to TGA approval, the test will be added to Atomo's existing ARTG listing. 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 and Atomo has committed to the submission of its product for assessment by the Doherty Institute upon listing on the ARTG.

Now that Atomo has secured exclusive distribution rights, Atomo will progress regulatory applications within its exclusive jurisdictions in the coming months and will keep the market informed of its progress. Based on an assessment of regulatory pathways, Atomo's initial focus will be Australia, the Philippines, Hong Kong and Taiwan.

Atomo's co-founder and Managing Director John Kelly said, "*Atomo is delighted to have secured exclusive rights to market, as the listed manufacturer, the COVID19 test which NG Biotech has successfully launched in Europe with initial sales to the French Ministry of the Armies (Defence) and a number of public hospitals, following strong results in independent French clinical studies.*"

[3] See https://www.chiefscientist.gov.au/sites/default/files/2020-04/COVID19%20serological%20antibody%20tests.pdf)

A study by Hopital Bicêtre, Bacteriologie Hygiene, France which tested 256 sera from 101 patients hospitalised with SARS-CoV-2 infection (positive RT-PCR), during the period 11 to 23 March 2020 for IgM and IgG using the NG Test IgG / IgM COVID19, has found that *"Sensitivity, Specificity, Positive Predictive Value and Negative Predictive Value were 97.0%, 100%, 100% and 96.2%, 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 copy of the paper (which is a pre-print of the Lancet Infectious Diseases and accordingly, has not been the subject of peer review) can be accessed via this link: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3582814.

We note that Dr Alan Finkel, Australia's Chief Scientist, provided a report to Minister Hunt titled 'The predictive value of serological testing during the COVID-19 pandemic' dated 30 April 2020[3] 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 above, the Hopital Bicêtre study of the COVID-19 antibody test demonstrated 100% specificity.

"*These results and the proven ease-of-use of Atomo devices in the field, in our opinion, make the test well suited to community deployment and population screening programs. With our exclusive agreement in place and the AtomoRapid COVID-19 (IgG/IgM) product having a CE Mark, we are now in a position to progress regulatory applications within our exclusive jurisdictions in the coming months,"* Mr Kelly continued.

AtomoRapid COVID-19 (IgG/IgM) is an integrated blood test device designed to determine if a patient has developed antibodies generated in the body in response to the COVID-19 virus. Results are obtained from a drop of blood in 15 minutes.

For more information, please contact:

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

John Kelly
Managing Director, Atomo
john.kelly@atomodiagnostics.com
Phone: +61 401 922 279

[3] See https://www.chiefscientist.gov.au/sites/default/files/2020-04/COVID19%20serological%20antibody%20tests.pdf)

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.