ASX Announcement **10 November 2020**

Atomo receives TGA approval for its *AtomoRapid™ HIV (1&2)* professional use rapid diagnostic test

Highlights:

- ***AtomoRapid™ HIV (1&2)* professional use rapid diagnostic test approved and listed on the Australian Register of Therapeutic Goods (ARTG)**
- **Handheld, single-use blood tests to be supplied to accredited laboratories and healthcare workers to perform HIV rapid testing in point of care settings**
- **Unlike laboratory-based testing where a patient may have to wait several days for their result, the Atomo test gives an accurate result in just 15 minutes**

SYDNEY Australia Tuesday, 10 November 2020: Atomo Diagnostics Limited (ASX: AT1) (**Atomo**) announces that the Therapeutic Goods Administration (**TGA**) has approved its *AtomoRapid HIV 1&2* rapid diagnostic test (**RDT**) for use by medical professionals in point of care settings in Australia. The product joins other Atomo products on the Australian Register of Therapeutic Goods (**ARTG**), including the *AtomoRapid COVID-19 Antibody Test, the Atomo COVID-19 Antigen Test,* and the *Atomo HIV Self-Test* - the first and only HIV self-test to have been approved for sale in Australia.

While there is no cure for HIV infection, antiretroviral (**ARV**) drugs can effectively control the virus and help prevent transmission, so that people with HIV can enjoy healthy, long, and productive lives. Early diagnosis is deemed essential in the global fight against HIV, with the convenience and prompt results offered by point of care testing being critical in this regard.

The *AtomoRapid HIV (1&2)* test detects the presence of HIV antibodies in a single drop of blood obtained from a fingertip. Unlike laboratory-based tests, where the patient may have to wait several days for their result to be returned, *AtomoRapid HIV (1&2)* gives an accurate test result in just 15 minutes, enabling same-day diagnosis and early access to treatment and care.

The test's unique design – comprising an inbuilt sterile safety lancet, patented blood collection and delivery mechanism, and a highly sensitive HIV diagnostic test strip – integrates necessary features and functionality in a single, handheld, easy-to-use device that is ideally

suited for deployment in sexual health screening, drop-in clinics, and community health programs.

Atomo's Managing Director, John Kelly, said: *"We are very pleased to have received TGA approval for our AtomoRapid HIV (1&2) professional use diagnostic test. We already manufacture and supply the only HIV self-test to have been approved for sale in Australia, so we see this latest approval as further confirmation of our expertise in this field. This latest good news follows our recent TGA approvals for rapid antigen and antibody tests that detect SARS-COV-2, the virus that causes COVID-19, and means we can now further expand our portfolio of best-in-class rapid diagnostic tests in our home market."*

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This announcement was authorised by John Kelly, Managing Director.

About Atomo

Atomo Diagnostics Limited is a world leader in medical device design and development, based in Sydney, Australia. The company specialises in creating integrated rapid diagnostic test (RDT) platforms for blood-based testing. The recipient of multiple international awards for innovation, Atomo's all-in-one AtomoRapid™ devices make it easy to test and screen for a range of infectious diseases and chronic conditions. Atomo's patented devices simplify testing procedures and enhance usability for professional users and untrained self-testers. As well as commercialising products in its own brand, Atomo provides OEM product development services to specialist diagnostic companies worldwide.

See more at www.atomodiagnostics.com.