CELLMID

ASX ANNOUNCEMENT

CELLMID SIGNS EXCLUSIVE AGREEMENT FOR SARS-CoV-2 LABORATORY TESTS

SYDNEY, Thursday, 9 July 2020: Cellmid Limited (ASX: CDY) is pleased to advise that it has signed an exclusive distribution agreement ("Agreement") with Immunodiagnostics Limited, Hong Kong (IMD) for laboratory based, quantitative Enzyme Linked Immunosorbent Assays (ELISA's) and a point of care serology test for SARS-CoV-2 for Australia and New Zealand (Agreement). ELISA's used for research only do not require TGA approvals, therefore Cellmid will initially seek regulatory approval from the TGA as well as import permits for a small selection of the devices, based on their immediate utility, with others to follow based on demand. Cellmid will order commercial quantities of the tests following regulatory approval.

The initial exclusivity period runs for six months from the date of signing the Agreement with subsequent time extensions negotiated by mutual agreement thereafter.

Cellmid already has two agreements in place to access point of care and laboratory-based SARS-CoV-2 testing devices (ASX Announcements, 27 March 2020, 4 June 2020 and 2 July 2020). The Agreement with IMD provides the Company with access to laboratory-based ELISA systems that can quantify the level and identify the type of antibodies against different SARS-CoV-2 antigens.

The key advantage of the ELISA technology is that it can measure absolute levels of antibodies against different SARS-CoV-2 antigens. In addition, ELISA's normally have lower level of detection limits compared to point of care devices increasing their accuracy. Routinely used in most laboratories ELISA systems are essential in vaccine trials, when monitoring the population after vaccine roll outs begin and, in tandem with point of care screening, in serological surveys.

Cellmid's partner, IMD, a spin off company from Hong Kong University and headed by Professor Aimin Xu, is dedicated to the discovery, development, manufacture, and distribution of *in vitro* diagnostics (IVD) for chronic and infectious diseases. IMD codevelops its tests with Toronto Bioscience Inc., (Canada), who also acts as North American distributor for the tests. All of the ELISA's are currently sold in Europe and Canada. The Immunodiagnostics branded tests are manufactured in IMD's facilities in Taiwan and China under ISO13485:2016 adhering to strict quality control and validation.

The first product Cellmid will focus on is the CE Marked SARS-CoV-2 S1 IgG ELISA Kit for the detection of IgG antibody specific for viral spike protein. Evaluation of the kit by the manufacturer and by Hong Kong University State Key Laboratory of Biotechnology using a stratified dataset comprising 273 confirmed COVID-19 patients and 542 pre-COVID-19 control samples showed specificity of 99.08% and sensitivities of:

- Day 0-7: 94.03% (n=67)
- Day 8-14: 96.20% (n=79)
- Day 14+: 100% (n=127)

Samples for the evaluations were sourced from the Centre for Disease Control at Dongguan City and Shenzhen Sixth People's Hospital in Shenzhen. The Agreement also covers additional ELISA tests including the SARS-CoV-2 NP IgM ELISA Kit, SARS-CoV-2 NP IgG ELISA Kit, SARS-CoV-2 NP total Antibody ELISA Kit and SARS-CoV-2 S1RBD IgG ELISA Kit[1]. The suite of available tests has broad utility in different research and clinical scenarios, allowing Cellmid to address various market needs.

In addition to the ELISA's, a high-quality point of care serology device is also included in the Agreement. The device detects both IgM and IgG specific to the nucleocapsid protein of SARS-CoV-2, differentiating it from the viral spike protein detecting kits already accessed by Cellmid. The Company is likely to seek regulatory approval from the TGA for the device.

Evaluation of the point of care test by the manufacturer and by Hong Kong University State Key Laboratory of Biotechnology using a stratified dataset comprising 273 confirmed COVID-19 patients and 542 pre-COVID-19 control samples showed an IgG sensitivity of 96.1% and specificity of 96.1% at the most relevant period of 14+ days following onset of symptoms and an IgM sensitivity of 91% and specificity of 97.4% at the most relevant period of 0-7 days from symptoms. Samples for the evaluations were sourced from the Centre for Disease Control at Dongguan City and Shenzhen Sixth People's Hospital in Shenzhen.

Approved for release by the Board of Directors of Cellmid.

End

Contact:
Maria Halasz, CEO
T +612 9221 6830
@mariahalasz

[1] The different ELISA kits measure antibodies that bind to different antigens on the SARS-CoV-2 virus. The specific antigen they bind to is incorporated in the name of the ELISA. The NP IgG ELISA measures IgG antibodies specific to the nucleoplasmid protein of the SARS-CoV-2 virus, the S1 IgG ELISA measures IgG antibodies specific to the spike protein of the SARS-coV-2 virus, the S1 RBD IgG ELISA measures antibodies specific to the receptor binding domain of the spike protein, the NP IgM ELISA measures the IgM antibodies specific to the nucleoplasmid protein of the SARS-CoV-2 virus and the NP Ab ELISA measures the total antibody specific to the nucleoplasmid protein of the SARS-CoV-2 virus.

Cellmid Limited (ASX: CDY)

Cellmid is an Australian life sciences company with a consumer health business and biotech assets in development. Advangen Limited is Cellmid's wholly owned subsidiary engaged in the development and sale of first in class, best in class, clinically validated anti-aging products for hair, skin and body. For further information, please see www.cellmid.com.au and www.evolisproducts.com.au. Cellmid's wholly owned subsidiary, Lyramid, develops innovative novel therapies and diagnostic tests for age related diseases including inflammatory and autoimmune conditions. Most recently Cellmid secured access to a range of SARS-CoV-2 antibody and nucleotide tests, both point of care and laboratory based, from various suppliers.

Forward looking statements

This announcement may have forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks that may cause the actual results, performance or achievements of Cellmid to be materially different from the statements in this announcement. Actual results could differ materially depending on factors such as the availability of resources, regulatory environment, the results of marketing and sales activities and competition.