

#### ASX ANNOUNCEMENT

# CELLMID SIGNS INTRODUCER AGREEMENT TO BROADEN PRODUCT OFFERING

- Cellmid signed an Introducer Agreement with Emergence Technology Pty Ltd (Emergence) securing access to additional SARS-CoV-2 tests for its customers.
   The tests include split IgG/IgM antibody manufactured by Zhuhai Livzon Diagnostics Inc (Livzon Test), as well as fluorescent and PCR based nucleotide detection analyzer and kits manufactured by Ustar Biotechnologies (HANGZHOU) Ltd (Ustar Test) (together, Tests).
- Emergence is responsible for the supply of the Tests. Emergence will be responsible for securing supply pursuant to its existing and future authorizations from the manufacturers, and for the various regulatory approvals and licenses for the sale of the Tests in countries where it intends to make a sale.
- The Tests are available to Emergence globally. The increased geographical reach will allow Cellmid to pursue expressions of interests it received, subject to local regulatory conditions, from outside of Australia.
- The Agreement allows for the payment of a Commission to Cellmid in relation to sales on introductions it makes to potential customers. The Commission is calculated on the gross margin of the relevant sales.

**SYDNEY, Thursday 4 June 2020: Cellmid Limited (ASX: CDY)** is pleased to advise that it has signed a non-exclusive Introducer Agreement (Agreement) with Emergence Technology Pty Ltd (Emergence). The Agreement allows Cellmid to introduce its current customers, parties it received expressions of interests from since 27 March 2020 and new customers, whether in Australia or overseas, (Customers) to Emergence, for the supply of the Tests, subject to local regulatory conditions and with the view to receive a Commission on sales.

Based in Melbourne, Emergence is a multidisciplinary company incorporated on 27 August 2019 and established to harness scientific expertise to solve real-world problems. Under the direction of sole director and shareholder, Mr Cun Liu, Emergence has established strong ties with manufacturers of medical devices in China and secured supply for the Tests. Per the Agreement, Emergence can nominate third parties (with Cellmid's consent) to facilitate the supply of the Tests to customers introduced by Cellmid.

The Agreement is effective immediately and will remain in force until such date as Emergence ceases to receive sales proceeds from Cellmid introduced Customers. Either party can terminate the agreement with 6 months' notice. Emergence's own agreements with the manufacturers last until at least May 2021 and include the ability to negotiate extensions.



As previously advised in the ASX announcement dated 27 March 2020, Cellmid currently has a supply agreement with Australia Application Pty Ltd (Australia Application) and is a TGA sponsor of the Wondfo SARS-CoV-2 antibody test (Lateral Flow Method) for distribution within Australia. Australia Application's agreement with Wondfo is valid until 30 June 2020 and may be extended if Wondfo provide written consent. Emergence is currently in negotiations with Wondfo to become a distributor of the Wondfo test in Australia and overseas. It is expected that, if Emergence is successful in becoming a distributor of the Wondfo test, Cellmid will be able to introduce customers to Emergence in overseas markets, as well as accessing supply through its existing agreement (with Australia Application) for Australia.

The Wondfo test detects IgM and IgG antibodies together in a single result strip. However, separate detection of IgM and IgG antibodies may be preferred for certain applications. Emerging scientific evidence has been consistent that using nucleotide and antibody tests together improves accuracy of diagnosis for COVID-19 patients. Securing access for Cellmid's Customers to a rapid nucleotide test has therefore been important to improve the SARS-CoV-2 diagnostic product portfolio.

Cellmid has previously advised the market (ASX announcement 21 May 2020) that it has been looking to broaden the SARS-CoV-2 diagnostic product range it can offer to its customers with both antibody and nucleotide tests. The Agreement with Emergence allows for a low cost and low risk option to achieve that.

In the same ASX announcement Cellmid has also advised the market that it intends to expand its geographic reach for the SARS-CoV-2 Tests beyond Australia. The Agreement allows it to introduce overseas Customers to Emergence and benefit from its contacts outside of Australia.

Emergence will be responsible to ensure regulatory compliance in any jurisdiction in which sales are to be made. They will also provide Cellmid with all clinical, assay related and marketing material before these are provided to Cellmid's Customers to ensure that the Tests are sold for appropriate use.

Whilst Cellmid is unable to forecast the number of sales Emergence is likely to make as a result of an introduction to a Customer and therefore has no indication of the Commission it is likely to receive, the Company does consider this to be a material agreement given it will allow pursuing the overseas expressions of interests it has received since 27 March 2020, and will broaden its product offering to its Customers.

The following SARS-CoV-2 products are included in the Agreement:

# Zhuhai Livzon Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Lateral Flow

The Livzon Test allows distinct measurement of IgG and IgM antibodies on separate devices. IgM is expected to be the first antibody seen after an infection, but has a low persistence, while IgG rises later in an infection and may persist for extended periods following recovery (Slide 11, ASX Announcement 21 May 2020). Separate



measurement of IgG and IgM may provide additional information to clinicians on the stage of the infection.

The Livzon Test is manufactured in China in an ISO13485:2016 facility, the international standard for medical quality management. The tests have been validated by the manufacturer using a 644-patient dataset. According to those patient samples the IgM device showed 79% sensitivity and 99.7% specificity, the IgG showed 84.3% sensitivity and 99.4% specificity. In combination the IgG and IgM device readouts led to 90.6% sensitivity and 99.2% specificity. Cross reactivity analysis of the kits showed no detection of common respiratory viruses including common respiratory coronaviruses.

Emergence is one of the sponsors of the Livzon Test which has been approved for inclusion on the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration. As with any SARS-CoV-2 antibody test on the ARTG (including the Wondfo Test) the Livzon Test is currently being independently reviewed by the Peter Doherty Institute for Infection and Immunity. The Doherty review is a post-market review by the TGA and it does not affect Cellmid's ability to introduce customers to Emergence, or Emergence's ability to make sales of the Livzon Test during that time in Australia or overseas. Cellmid has no involvement in the Doherty review of the Livzon Test and no liability whether the result will be consistent with the manufacturer's specifications or not.

The Livzon Test is also CE Marked and currently has an application pending for emergency use (EUA) with the Food and Drug Administration (FDA) in the USA. In the event the application is unsuccessful, Emergence will only be able to sell to Customers in the USA that operate in an approved pathology laboratory.

# Ustar Biotechnologies nucleic acid detection diagnostics

Ustar Biotechnologies manufactures diagnostic devices for the detection of nucleic acid in samples. Nucleic acid detection is the accepted standard for acute diagnosis of COVID-19 and represents an important addition to Cellmid's product offerings. The advantage of the Ustar platform is that it consists of an all-in-one sample preparation and reaction cartridge, coupled with an analyzer.

As the system requires minimal sample handling and processing, is it simple to use and can deliver results quickly, it lends itself to resource limited, remote or mobile locations, particularly in geographies where there is lack of expertise and access to dedicated laboratories. The PCR detection kit was tested on behalf of the manufacturer using 589 confirmed COVID-19 samples and showed 96.3% sensitivity (95% CI) and 100% specificity (95% CI).

The Ustar products are manufactured in China, they are CE Marked, approved for inclusion on the ARTG and currently have an application pending for emergency use with the FDA in the USA. In the event the application is unsuccessful, Emergence will only be able to sell to Customers in the USA that operate in an approved pathology laboratory. The Ustar tests detect viral nucleotides and are not subject to testing by the Doherty Institute.



Cellmid notes that the sponsor of the Ustar test on the ARTG (eHealthy Pty Ltd) is not related to Emergence and that Emergence's approval to supply the tests in Australia is under the TGA's emergency exemption to accredited pathology laboratories which remains in force until 31 January 2021. Cellmid will introduce customers to Emergence that have approved pathology labs.

"We are excited to be able to broaden the SARS-CoV-2 diagnostic portfolio for our Customers and be able to refer them to different tests for different use" said CEO Maria Halasz.

Approved for release by the Board of Directors.

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### 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 <a href="www.cellmid.com.au">www.cellmid.com.au</a> and <a href="www.cellmid.com.a

## 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.