ASX ANNOUNCEMENT

CELLMID REPORTS ON RESULTS OF THE DOHERTY INSTITUTE TESTING

SYDNEY, Monday, 15 June 2020: Cellmid Limited (ASX: CDY) is pleased to provide the following report in relation to the results of the testing of the Wondfo SARS-CoV-2 Antibody Tests (Lateral Flow) (Wondfo Test) by the Doherty Institute (interim Doherty Report).[1] The interim Doherty Report was produced by the Doherty Institute for the Therapeutic Goods Administration (TGA) as part of its post market review of all serology-based COVID-19 POC tests on the ARTG (Australian Therapeutic Goods Register) to verify their ability to detect antibodies to SARS-COV-2 (the virus that causes COVID-19).

The results of the interim Doherty Report and Wondfo's own clinical validation study results are included in the table below. The interim Doherty Report's results indicate testing against polymerase chain reaction (PCR) tested patient samples and do not represent evaluation in a clinical setting, unlike Wondfo's own validation.

Table: Performance of Wondfo Test in the interim Doherty Report and manufacturer's specifications

Wondfo kit	Doherty /TGA reported value	Wondfo clinical data as reported to TGA
Sensitivity all time points	68.6% (95% CI: 60.1-76.3)	86.4% (95% CI: 82.5-89.6)
Sensitivity 9-14 days	76.2% (95% CI: 52.8-91.8)	85.2% (95% CI: 78.7-89.9)
Sensitivity 15 days +	93.8% (95% CI: 85.0-98.3)	94.3% (95% CI: 87.2-97.5)
Specificity	97.8% (95% CI: 92.4-97.9)	99.6% (95% CI: 97.6-99.9)

The overall sensitivity (true positives) by the interim Doherty Report of the Wondfo test is 68.6%, the Wondfo stated overall sensitivity was 86.43%. The sensitivity in the periods after the expected development of the antibodies (14+ days) is 93.8% in the interim Doherty Report, while Wondfo stated sensitivity during the same period was 94.24%. The interim Doherty Report specificity (true negatives) was 97.8%, while the Wondfo reported specificity was 99.57%.

Cellmid CEO, Maria Halasz said, "Whilst it is noted that there are still seventeen other tests listed on the ARTG to be reviewed, we are very pleased to see that the results of

[1] https://www.health.gov.au/sites/default/files/documents/2020/06/post-market-validation-of-serological-assays-for-covid-19-updated-report_0.pdf

the review outlined in the interim Doherty Report make the Wondfo Test one of the best performing of the five antibody tests reviewed to date across all specificity and sensitivity metrics. The testing showed performance results which are consistent with the manufacturer's claims in the meaningful period of 14+ days following onset of symptoms, when antibodies are expected to be present in most patients."

Cellmid, as an ARTG (Australian Therapeutic Goods Register) sponsor for the Wondfo Test, submitted 250 tests from two different manufacturing batches each for post market review by the Doherty Institute. The interim Doherty Report includes four other SARS-CoV-2 antibody devices reviewed to date and allows for a comparison between those as well as with Wondfo's own clinical validation data.

Whilst the interim Doherty Report concludes that the Wondfo Test's overall sensitivity of 68.6% is below the manufacturer's reported 86.43%, it also states that the Wondfo Test achieves the manufacturer's stated performance when serum samples collected greater than 14 days following the onset of symptoms are included only.

In comparison with the other four tests reviewed to date, the Wondfo Test had the highest overall sensitivity of 68.6% amongst the five devices tested when including samples from day 0 to 3 days from onset of symptoms, when there is little or no antibody is likely to be produced by the body. The interim Doherty Report of the Wondfo Test also reported equal highest sensitivity of 93.8% at 14+ days from onset of symptoms. and a specificity of 97.8%. It should be noted that there are still seventeen tests listed on the ARTG to be reviewed.

Cellmid has provided information to the TGA on the clinical studies completed by Wondfo to support the performance of the Wondfo Test. The Company submitted data to the TGA with stratification of the results according to different periods post onset of symptoms. These data points have been presented in the Table above. This is the same information that is used for comparing the manufacturer's claims against the Doherty Institute's findings by the TGA. Cellmid has not received any advice from the TGA to date in relation to the need for any subsequent regulatory action.

There are differences between the Doherty Institute testing and Wondfo's own validation studies which in the Company's opinion can fully explain where there are differences between the results. These details are set out in the SCHEDULE below. Whilst the interim Doherty Report states that: "*Our findings strongly suggest that PoCT devices should not be used in the diagnosis of acute COVID-19, and have limited, if any, role in clinical management of individual patients*" Cellmid notes that this is consistent with its previous statements and the manufacturer's instructions for use.

In its commentary on the interim Doherty Report the TGA state: "*As yet not enough is known about the adequacy of the COVID-19 immune response or duration of immunity. Whether there is a role for these tests in determining immunity for return to work purposes or for population-level surveillance remains to be seen.*"

However, there is a growing body of evidence that serology-based assays increase the accuracy and speed of diagnosis when combined with PCR methods and

assessment of clinical symptoms[2],[3]. Furthermore, a population study by the Spanish government used a point of care antibody device, such as the Wondfo Test with similar performance to the Wondfo Test[4], to assess 60,000 people for the prevalence of SARS-CoV-2 antibodies.

Importantly, and most recently, the Institute for Global Change, a government advisory organization, has delivered its analysis and recommendations on testing[5]. It foreshadowed that as the pandemic progresses serological testing, including point of care devices, will have an important place in widespread population surveys, in research and development activities such as drug and vaccine trials, in return to work scenarios and as an adjunct device in diagnostic and triage settings in the event of reemergence.

SCHEDULE - Differences between the Doherty Institute testing and Wondfo's clinical validation

Wondfo conducted its testing on a larger sample size, with greater statistical power, comprising 596 patient samples (361 samples for sensitivity and 235 samples for specificity), whereas the Doherty Institute tested 137 samples from 91 patients to evaluate sensitivity and 92 samples from 92 patients for specificity.

Wondfo included patients that had a confirmed diagnosis based on clinical evaluation guidelines and polymerase chain reaction (PCR) nucleotide testing. The interim Doherty Report notes their reliance on samples from patients confirmed by PCR only, without disclosing secondary sampling or confirmatory testing. It is reported in scientific literature that PCR testing is prone to both false positive and false negative results [6].

Current studies show marked variation and are likely to overestimate sensitivity, therefore it is suggested that the lower end of current estimates from systematic reviews to be used with the approximate numbers of 70% for sensitivity and 95% for specificity for illustrative purposes."[7] In short, in Cellmid's opinion, PCR results can confound diagnosis if used as the sole measure and may result in false positive and false negative samples used to compare accuracy of the antibody tests.

The Wondfo patient samples were weighted towards more severe cases presenting to hospitals in China early in the pandemic. In Cellmid's opinion, the interim Doherty Report, due to the composition of the Australian patient cohort generally, is likely to include more of the less severe or asymptomatic cases. In Cellmid's opinion these

[2] Clinical Infectious Diseases (2020).Guo *et al*,. "Profiling early humoral response to diagnose novel coronavirus disease (COVID-19)."
[3] Clinical Infectious diseases (2020) Zhao *et al*., Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019
[4] https://www.the-scientist.com/news-opinion/researchers-applaud-spanish-covid-19-serological-survey-67590
[5] https://institute.global/policy/changing-game-testing
[6] Allergy (Eur J Allerg Clin Immunol) 2020, Azkur *et al*., Immune response to SARS-CoV-2 and mechanisms of immunopathological changes in COVID-19, amongst others
[7] https://www.bmj.com/content/369/bmj.m1808

differences can make a direct comparison difficult and instruct on the inherent differences in the results, as severe cases carrying high viral load may have different seroconversion profiles to milder cases.

Cellmid CEO, Maria Halasz said "As a life sciences company with significant diagnostics expertise these positive results confirmed our confidence in the Wondfo Test, which we continue to promote in addition to our broader portfolio of diagnostic products as new applications emerge."

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. 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 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, the Company commenced sale of rapid tests for SARS-CoV-2.

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.