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ASX and MEDIA RELEASE

Dotz completes successful clinical trial; submits FDA Emergency Use Authorisation application

Dotz Nano Limited (ASX:DTZ) ("**Dotz**" or the "**Company**") an advanced technology company developing, manufacturing and commercialising marking, tracing and verification solutions, has made an application to the U.S. Food and Drug Administration ("**FDA**") for an Emergency Use Authorisation ("**EUA**") for distribution and/or use of its SARS-CoV-2 virus detection technology (the "**Dotz Test Kits**") in respect of nasopharyngeal/oropharyngeal swab samples only.

As part of its FDA EUA application, Dotz was required to complete a clinical trial of at least 30 COVID-19 positive and 30 COVID19 negative subjects with a broad range of viral loads. Patient nasopharyngeal swab samples were acquired from US-based iQ Genetix1, and sample positivity of these samples was first tested using the Dotz Test Kit and then confirmed using the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel in accordance with FDA requirements. In total, in the evaluation performed by Caerus and on behalf of Dotz on 73 subjects located in the United States, 31 positive patient samples and 42 negative patient samples were identified.

The blinded clinical trial produced the following results:

- 96.77% positive agreement between the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel;
- 100% negative agreement between the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel;
- Limit of Detection (LoD) of 2,500 copies per mL; and
- 100% specificity, which is the ability to identify SARS-CoV-2 without being triggered by other viruses.

Percent Positive Agreement	96.77%
False Negative Rate	3.23%
False Positive Rate	0.00%
Percent Negative Agreement	100.00%
Number of Positives	31
Number of Negatives	42
Total Samples	73

Clinical evaluation results

While the Dotz Test Kit has obtained CE Mark authorisation for both nasopharyngeal swab and saliva-based samples, which clears it for sale in the European Union (although some countries in the European Union have additional import regulatory requirements that Dotz will need to comply with if it intends to sell the Dotz Test Kits in those countries), the FDA EUA application is based only on nasopharyngeal/oropharyngeal swab samples to simplify the application process. The standard method of sample collection in most parts of the world is nasopharyngeal swab sampling. Dotz is engaging with the FDA to clarify the proper saliva-based comparator assay, and intends to make a secondary FDA EUA application for the Dotz Test Kit in respect of saliva samples, already collected and delivered by Excelya, by the end of April 2021. As part of this secondary FDA EUA application, the Company may or may not be required to undertake further clinical trials (this will ultimately be determined by the FDA).

[1] iqgenetix.com/about-us/

As previously announced by the Company on 1 and 22 March 2021, both the nasopharyngeal swab and the saliva-based Dotz Test Kit has the following features:

- 100% specificity, following a negative cross-reactivity results for a range of other viruses;
- Test results within 15-17 minutes (when using two heating blocks);
- Visual detection by colour change of the reagents; and
- Simultaneous testing of up to hundreds of samples using standard heating blocks (other materials including a viral RNA extraction kit are required for testing but not included in the Dotz Test Kit).

In line with Dotz's CE Mark application, the Company has engaged and listed US-based manufacturer Systaaq Diagnostic Products as the ISO13485 manufacturer for its nasopharyngeal swab and saliva-based Dotz Test Kits.

Dotz is not able at this time to provide with any certainty an estimated timeline for receipt of its FDA EUA in respect of the Dotz Test Kit. There is also no certainty that the FDA will provide Dotz with the EUA in respect of the Dotz Test Kit, whether for the nasopharyngeal swab Dotz Test Kits and/or, upon submission, the saliva-based Dotz Test Kits.

If the FDA provides Dotz with the EUA in respect of the Dotz Test Kit, the Company understands that it is possible that the following terms and conditions could be attached to the EUA (however the final terms and conditions (if any) will ultimately be determined by the FDA):

- the EUA would only be in effect for the duration of the COVID-19 declaration by the US Secretary of Health and Human Service justifying emergency use of in vitro diagnostics (IVDs), unless terminated or revoked (after which time the Dotz Test Kit would no longer be able to be used); and
- under an EUA, the Dotz Test Kit would only be likely to be authorised for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

For completeness, it is noted that IVDs made available under an EUA do not undergo the same type of review as an FDA approved or cleared IVD.

Commenting on the FDA EUA application, Dotz Chairman and Interim CEO Bernie Brookes said, "We are encouraged by the results of our blinded clinical trial, which demonstrated the effectiveness of our Dotz Test Kits in correctly identifying the SARS-CoV-2 virus. If the Company's FDA EUA application is successful and FDA EUA is obtained, such will enable Dotz to sell and distribute its virus detection technology in respect of nasopharyngeal/oropharyngeal swab samples within the large US market (for the duration of the COVID-19 declaration by the US Secretary of Health and Human Service justifying emergency use of IVDs, and subject to any terms and conditions of the EUA), which is currently experiencing an average of more than 1 million COVID-19 tests per day."

-ENDS-

This announcement has been authorised for release by the Board of Dotz Nano Limited.

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About Dotz Nano Limited

Dotz Nano Limited (ASX: DTZ) is a technology leader in research, production and marketing of anti-counterfeiting, authentication and tracing solutions.

Its unique products ValiDotz, BioDotz, Fluorensic and InSpec are exceptional solutions for numerous applications, such as: bio-imaging, liquids tagging, lubricants and DEF authentication, polymers tagging, anti-counterfeiting, brand & reputation protection and oil & gas industry.

To learn more about Dotz, please visit the website and corporate video via the following link www.dotz.tech