

# FDA Emergency Use Authorization for COVID-19 test

RNS Number : 1209H

Novacyt S.A.

23 March 2020

Novacyt S.A.

("Novacyt" or the "Company")

US FDA Emergency Use Authorization for COVID-19 diagnostic test

COVID-19 RUO test receives approval in Indonesia

Paris, France and Camberley, UK - 23 March 2020 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, is pleased to announce that the US Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for its COVID-19 test. As a result, hospitals and laboratories in the US will be able to use the test for clinical diagnosis of COVID-19. The test is available for immediate distribution into the US market.

Primerdesign, the Company's molecular diagnostics division, launched the COVID-19 test as a research use only (RUO) test on 31 January 2020 and as a CE-Mark test on 17 February 2020. The benefits of the Primerdesign test include:

- Proven high performance characteristics
- Provides results in less than two hours
- Being lyophilised (freeze-dried), it is stable to be shipped at ambient temperature
- Can be used on multiple ubiquitous clinical laboratory instrument platforms

The Company is also pleased to announce that its RUO COVID-19 test has also been approved by the Indonesian Ministry of Health, which opens another new market for its test.

Graham Mullis, Chief Executive Officer of Novacyt, commented:

"The US FDA EUA authorization is another important endorsement of the performance and quality of our COVID-19 test and demonstrates once again Novacyt's growing role in tackling this pandemic. We are committed to providing clinicians around the world with our COVID-19 test and delighted we can now support the US market."

#### About Emergency Use Authorization Status

The Primerdesign COVID-19 test has been authorized by the FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform moderate and high complexity tests. The test has been authorized only for the detection of RNA from SARS-CoV-2 virus and diagnosis of SARS-CoV-2 virus infection, not for any other viruses or pathogens. It is authorised for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection of SARS-CoV-2 virus under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the authorisation is terminated or revoked sooner.

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014.

- End -

#### Contacts

Novacyt SA

Graham Mullis, Chief Executive Officer

Anthony Dyer, Chief Financial Officer

+44 (0)1276 600081

SP Angel Corporate Finance LLP (Nominated Adviser and Broker)

Matthew Johnson / Charlie Bouverat (Corporate Finance)

Vadim Alexandre / Rob Rees (Corporate Broking)

+44 (0)20 3470 0470

FTI Consulting (International)

Victoria Foster Mitchell / Mary Whittow

+44 (0)20 3727 1000

[victoria.fostermitchell@fticonsulting.com](mailto:victoria.fostermitchell@fticonsulting.com) / [mary.whittow@fticonsulting.com](mailto:mary.whittow@fticonsulting.com)

FTI Consulting (France)

Arnaud de Cheffontaines

+33 (0)147 03 69 47

arnaud.decheffontaines@fticonsulting.com

#### About Novacyt Group

The Novacyt Group is an international diagnostics business generating an increasing portfolio of in vitro and molecular diagnostic tests. Its core strengths lie in diagnostics product development, commercialisation, contract design and manufacturing. The Company's lead business units comprise of Primerdesign and Lab21 Products, supplying an extensive range of high-quality assays and reagents worldwide. The Group directly serves microbiology, haematology and serology markets as do its global partners, which include major corporates.

For more information please refer to the website: [www.novacyt.com](http://www.novacyt.com)

#### About COVID-19

Researchers at the Chinese Centre for Disease Control and Prevention and their collaborators have sequenced the 2019 novel coronavirus (COVID-19) pathogen from patient samples and have found it to be genetically distinct from the severe acute respiratory syndrome (SARS) virus that caused an epidemic in 2002 and 2003, as well as from the Middle East respiratory syndrome (MERS) virus that was detected in 2012.

This information is provided by RNS, the news service of the London Stock Exchange. RNS is approved by the Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact [rns@lseg.com](mailto:rns@lseg.com) or visit [www.rns.com](http://www.rns.com).

END

UPDUUVRRRBUOUUR