Approval of COVID-19 test under CTDA legislation

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Novacyt S.A.
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("Novacyt", the "Company" or the "Group")

Approval of the first direct-to-PCR COVID-19 test in the UK under CTDA legislation

Paris, France and Camberley, UK - 17 February 2022 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, announces that the Company's PROmate® COVID-19 2G Real-Time PCR test has been approved in the UK under the UK Health Security Agency's Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 ("CTDA").

The PROmate® COVID-19 2G test is the first direct-to-PCR product to be added to the CTDA register of approved products and is designed to detect two SARS-CoV-2 targets within ORF1ab in response to an increasing shift from single-gene to multi-gene testing solutions. Direct-to-PCR products remove the need for complex, manual or automated extraction solutions and are designed to significantly improve laboratory workflow and reduce costs. It also allows testing to take place away from traditional, laboratory-based settings due to simplicity and ease of use. Therefore, the PROmate® COVID-19 2G PCR test is well suited for industries such as travel, sport, film, media, and workplace settings.

The validation of the PROmate® COVID-19 2G test follows the UK approval of the Company's COVID-19 genesig® Real-Time PCR test under the CTDA, as announced on 26 November 2021. In addition, as previously announced, Novacyt's PROmate® COVID-19 1G Real-Time PCR test, currently being supplied to the NHS under a National Microbiology Framework, remains on the temporary protocol list (due to expire on 28 February 2022) and the Company awaits further updates on an additional seven products submitted to the CTDA across its COVID-19 testing portfolio.

David Allmond, Group CEO of Novacyt, commented:

"Our PROmate® COVID-19 range offers a unique combination of workflow efficiency, results in as little as 80 minutes and exceptional clinical performance, optimised for both our genesig® q16 and q32 instruments. It provides total viral inactivation, with a ready-prepared mix containing internal control for run validity, meaning there is no need for a category 2 laboratory to handle the live virus, thereby removing handling risk and bringing the test nearer to patients. With this approval from the CTDA, we can continue to meet the demand for high quality COVID-19 testing in the UK."

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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

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