Validation of COVID-19 tests in the UK under CTDA

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

Validation of COVID-19 tests in the UK under CTDA legislation

Paris, France and Camberley, UK - 2 November 2021 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, announces an update on the availability of its COVID-19 tests in the UK following implementation of the UK Health Security Agency's Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 ("CTDA").

The mandatory CTDA guidelines require all suppliers of COVID-19 tests (polymerase chain reaction and antigen/lateral flow tests) to submit data on their tests for a desktop validation if they wish to continue to sell them in the UK. This legislation does not apply or affect any sales outside the UK.

On 20 October 2021, the UK Health Security Agency issued a list of products on the CTDA register that had so far successfully completed CTDA desktop review and been approved. A second list, the temporary protocol, was also issued detailing products which can remain on the market whilst validation is being processed with an extended deadline from 1 November 2021 to 28 February 2022. Only validated products, or products on the temporary protocol, can be sold in the UK after 31 October 2021. The UK Health Security Agency has committed to continuing its review of submitted tests and updating the CTDA register accordingly.

Novacyt submitted 11 products for review on time to meet the original CTDA submission deadline of 1 September 2021. To date, Novacyt's Primerdesign Ltd PROmate® COVID-19 test has been named on the temporary protocol (this encompasses both the PROmate® 1 Gene q16 and q32 products). The CTDA has not yet communicated the status of any of the remaining nine products.

As a result, from 1 November 2021, the Company will only be selling the PROmate® COVID-19 test in the UK until such time the UK Health Security Agency completes its review of the additional nine products submitted. If no further products are added to the CTDA register, the impact on full year revenues for 2021 will be circa £3 million.

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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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