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 second direct-to-PCR COVID-19 test in the UK under CTDA legislation

Paris, France and Camberley, UK - 12 April 2022 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, announces that the Company's PROmate® COVID-19 1G (q32) 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 1G test for use on Novacyt's q32 instrument is the Company's second direct-to-PCR and third product to be added to the CTDA register of approved products. The test is designed to detect a SARS-CoV-2 gene target within ORF1ab and, as with all the Company's direct-to-PCR products, removes the need for complex, manual, or automated extraction solutions to significantly improve laboratory workflow and reduce costs. The test was previously on the CTDA Temporary Protocol list of products which can continue to be sold in the UK whilst validation is being processed.

As previously announced, Novacyt's PROmate® COVID-19 1G test for use on the Company's q16 instrument (currently on the Temporary Protocol list) continues to be supplied to the NHS under a National Microbiology Framework.

Please see below the status of the 11 products Novacyt submitted to the CTDA before the deadline of 1 September 2021. The Company awaits further updates on the products submitted to the CTDA across its COVID-19 testing portfolio.

#	Product name	Current CTDA status
1	genesig® COVID-19 Real-Time PCR	Approved November 2021
2	PROmate® COVID-19 2G	Approved February 2022
3	PROmate® COVID-19 1G (q32)	Approved April 2022
4	PROmate® COVID-19 1G (q16)	On Temporary Protocol*

5	genesig® COVID-19 3G Real-Time PCR	
6	genesig® Real-time PCR SARS-CoV-2 Winterplex	
7	exsig™ COVID-19 direct	Evaluation in progress
8	SARS-CoV-2 Antigen Rapid	
9	genesig® COVID-19 3G HT	
10	genesig® Real-Time PCR COVID-19 HT	Withdrawn **
11	genesig® COVID-19 2G Real-Time PCR	

* Temporary Protocol list due to expire on 31 May 2022.

** Following feedback from the UK HSA and significantly diminished market demand for these particular products, the Company has decided not to pursue approval any further. Demand for these products can be substituted with other products in the Company's portfolio.

David Allmond, Group CEO of Novacyt, commented:

"Our PROmate® COVID-19 range remains at the forefront of COVID-19 testing for busy laboratories and clinicians requiring workflow efficiency, combined with exceptional clinical performance. Providing total viral inactivation without the need for a category 2 laboratory to handle the live virus, our PROmate® tests reduce handling risk and help bring testing nearer to patients. We look forward to continuing to meet the demand for high quality COVID-19 testing in the UK, as well as leveraging our direct-to-PCR technology for new disease targets in future."

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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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