CTDA approval and CE mark

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Novacyt S.A.
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Novacyt S.A.

("Novacyt", the "Company" or the "Group")

CTDA approval of PROmate® COVID-19 1 Gene and grant of CE mark for COVID-19 lateral flow self-test

Paris, France and Camberley, UK - 1 June 2022 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, announces the approval of its PROmate® COVID-19 1G (q16) Real-Time PCR test (for use on its Q16 instrument), by the UK Health Security Agency's Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 ("CTDA"). The Company also announces that the Company's PathFlow® COVID-19 Rapid Antigen Self-Test has received a CE mark.

Approval of PROmate® COVID-19 1 Gene

The Company was informed on 31 May, 2022, that PROmate® COVID-19 1G (q16) Real-Time PCR test has now been approved by the CTDA. The PROmate® COVID-19 1G test, for use on Novacyt's q16 instrument, is the Company's third direct-to-PCR and fourth 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.

Separately, the Company awaits further updates on the remaining products submitted to the CTDA across its COVID-19 testing portfolio, the current status of which is as follows:

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

4	PROmate® COVID-19 1G (q16)	Approved May 2022
5 6 7 8 9	genesig® COVID-19 3G Real-Time PCR genesig® Real-time PCR SARS-CoV-2 Winterplex exsig™ COVID-19 direct PathFlow® COVID-19 Rapid Antigen Pro PathFlow® COVID-19 Rapid Antigen Self-Test	Pending evaluation
10 11 12	genesig® COVID-19 3G HT genesig® Real-Time PCR COVID-19 HT genesig® COVID-19 2G Real-Time PCR	Withdrawn*

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

PathFlow® COVID-19 Rapid Antigen Self-Test

The PathFlow® COVID-19 Rapid Antigen Self-Test is one of the first saliva-based COVID-19 tests to be launched in the EEA and provides diagnosis of symptomatic and asymptomatic individuals in approximately 15 minutes. The single-use test is designed for home use with self-collected, non-invasive and easy to obtain oral fluid samples.

The CE mark ensures that the self-test is approved for sale in all 30 EEA countries. In the UK, the test will now be submitted for approval under the UK Health Security Agency's Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021 ("CTDA") to enable it to be sold in the UK. This self-test complements Novacyt's existing professional use test for detecting SARS-CoV-2, PathFlow® COVID-19 Rapid Antigen Pro, which has already received its CE mark.

David Allmond, Group CEO of Novacyt, commented:

"We are delighted to receive this CE mark for our saliva-based lateral flow self-test for COVID-19, one of the first tests for SARS-CoV-2 using this type of easy sample collection and accurate results in as little as 15 minutes. Following UK validation under CTDA legislation of a number of key products in our COVID-19 portfolio over the last six months, we are well placed to continue servicing our customers' COVID-19 testing needs in the UK. Looking ahead and more broadly, we are applying the learnings gained during the pandemic, as well as our proven track record and innovative technology to create diagnostics for new disease targets, set out in our recent growth strategy update, as we look to become a leading, global clinical diagnostics company."

The information contained within this Announcement is deemed by the Company to constitute inside information as stipulated under Article 7 of the Market Abuse Regulation (EU) No. 596/2014 (as amended) as it forms part of the domestic law of the United Kingdom by virtue of the European Union (Withdrawal) Act 2018 (as amended). Upon the publication of this Announcement via the Regulatory Information Service, this inside information is now considered to be in the public domain.

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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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