Approval of genesig COVID-19 3G PCR test in UK

RNS Number : 6734I
Novacyt S.A.
06 December 2022

Novacyt S.A.

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

Approval of genesig® COVID-19 3G PCR test in the UK under CTDA legislation

Paris, France and Eastleigh, UK - 6 December 2022 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, announces that the Company's genesig® COVID-19 3G 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"), making it the Company's seventh PCR test to be added to the CTDA register of approved COVID-19 diagnostic products.

The genesig® COVID-19 3G test, CE marked in April 2021, is designed to detect three separate SARS-CoV-2 gene targets (ORF1ab, M gene, and S genes) from combined nasal and oropharyngeal sample types. As seen during the COVID-19 pandemic, the prevalence of mutations with biological significance within the spike protein of SARS-CoV-2 meant the need to test for more than one gene target at a time increased.

James McCarthy, Acting Group CEO of Novacyt, commented:

"The approval of our COVID-19 3G test, our seventh product to be approved under the UK's CTDA legislation, reinforces the market-leading quality of our tests. We believe the ability of our COVID-19 3G test to simultaneously target three separate genes within SARS-CoV-2 provides a highly accurate option for detection. This latest approval ensures we are well-positioned with our consolidated COVID-19 portfolio for any potential future outbreaks and as we continue to focus on our wider diagnostic product offering as part of our growth strategy."

The status of the Company's current CTDA submissions 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	exsig™ COVID-19 Direct	Approved July 2022
6	genesig® Real-time PCR SARS-CoV-2 Winterplex	Approved 20 October 2022
7	genesig® COVID-19 3G Real-Time PCR	Approved 1 December 2022
8 9	PathFlow® COVID-19 Rapid Antigen Pro PathFlow® COVID-19 Rapid Antigen Self-Test	Pending evaluation

- End -

For further information, please refer to www.novacyt.com or contact:

Contacts

Novacyt SA

James Wakefield, Non-Executive Chairman

James McCarthy, Acting Chief Executive 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

Numis (Joint Broker)

Freddie Barnfield / James Black

+44 (0)20 7260 1000

Allegra Finance (French Listing Sponsor)

Rémi Durgetto / Yannick Petit

+33 (1) 42 22 10 10

r.durgetto@allegrafinance.com/ y.petit@allegrafinance.com

FTI Consulting (International)

Victoria Foster Mitchell / Alex Shaw

+44 (0)20 3727 1000

victoria.fostermitchell@fticonsulting.com / Alex.Shaw@fticonsulting.com / Novacyt.group@fticonsulting.com

FTI Consulting (France)

Arnaud de Cheffontaines

+33 (0)147 03 69 48

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 supplies 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

END

REAEAEASEAFAFAA