CORRECTION: UK CTDA approval of Winterplex 3G

RNS Number : 4115E
Novacyt S.A.
27 October 2022

This is a correction to the "UK Approval of genesig® SARS-CoV-2 Winterplex® 3G" announcement published at 7:00am on 26 October 2022 (RNS number 0989E) which incorrectly stated that Winterplex® 3G could use sputum and nasopharyngeal samples rather than anterior nasal samples (in addition to oropharyngeal samples)for the detection of influenza A, influenza B, respiratory syncytial virus (RSV), and SARS-CoV-2 (COVID-19) (specifically the detection of ORF1ab, S and M genes targets).

All other information remains unchanged. The full corrected announcement is included below.

Novacyt S.A.

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

Correction: Approval of genesig® SARS-CoV-2 Winterplex® 3 Gene assay panel in the UK under CTDA legislation

A multiplex PCR test for the detection of winter viruses including SARS-CoV-2, influenza A and B, and RSV

Paris, France and Camberley, UK - 27 October 2022 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, announces that the Company's genesig® Real-Time PCR SARS-CoV-2 Winterplex® 3G assay panel (Winterplex® 3G) 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 sixth PCR test to be added to the CTDA register of approved COVID-19 diagnostic products.

Winterplex® 3G is a high throughput multiplex screening assay (with 96 reactions per kit) for the detection of influenza A, influenza B, respiratory syncytial virus (RSV), and SARS-CoV-2 (COVID-19) (specifically the detection of ORF1ab, S and M genes targets) from oropharyngeal and anterior nasal samples.

This approval comes in advance of the winter virus season in the northern hemisphere and means the Company

can now sell Winterplex® 3G in the UK. Winterplex® 3G allows healthcare systems to differentiate between common respiratory infections which present with similar symptoms. As the prevalence of winter viruses increases, Novacyt continues to monitor all strains of influenza A, influenza B, RSV and SARS-CoV-2 through its bioinformatics surveillance programme.

David Allmond, Group CEO of Novacyt, commented:

"We are pleased Winterplex® 3G has been approved under the UK's CTDA legislation. This product is a combined assay which offers the benefit of testing for multiple seasonal viruses at the same time, saving time and requiring only one patient sample. We believe this is important as the diagnostics market moves towards favouring respiratory panels over COVID-19-specific testing due to concerns about the dual rise in COVID-19 and influenza cases this winter. 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 respiratory 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	Pending evaluation
8	PathFlow® COVID-19 Rapid Antigen Pro	
9	PathFlow® COVID-19 Rapid Antigen Self-Test	

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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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