R&D and UK operational update

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

R&D and UK operational update

Paris, France and Camberley, UK - 23 April 2021 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, announces an update on the progress of its near-term COVID-19 research and development (R&D) programmes to address rapidly evolving testing demands, particularly as SARS-CoV-2 continues to mutate around the world. Novacyt also provides an update on its UK operations.

R&D highlights

· Expansion of PathFlow® lateral flow test (LFT) portfolio with COVID-19 tests

o Launch of LFT to detect SARS-CoV-2 IgG antibodies

o Development of LFT to detect and differentiate between SARS-CoV-2 IgG antibodies, launch expected Q3 2021

o Development of LFT to detect antigens for SARS-CoV-2, launch expected by end of Q2 2021

· Expansion of genesig® COVID-19 polymerase chain reaction (PCR) portfolio

o Launch of CE Mark three-gene target PCR test

· Expansion of PROmate™ COVID-19 PCR portfolio for workflow efficiency in a near-to-patient setting

o Development of two-gene target test, launch expected May 2021

o Launch of test to identify a key mutation, E484K, found in all current variants of concern (VOC)

· Expansion of SNPsig® COVID-19 PCR genotyping portfolio to detect SARS-CoV-2 variants

o Launch of CE Mark VariPLEX™ assay panel to detect multiple variants

o Development of test to detect a variant originally identified in India, launch expected week commencing 26 April 2021

UK operational highlights

· Expansion of UK commercial infrastructure

· Inclusion in Public Health England (PHE) National Framework Agreement

Graham Mullis, Chief Executive Officer of Novacyt, commented:

"The continued development and expansion of our COVID-19 portfolio demonstrates Novacyt's ability to match the rapid evolution of SARS-CoV-2 with real-time bioinformatics surveillance and accelerated product development. We remain committed to identifying patient needs and overcoming healthcare challenges today and in the years ahead as we continue to strengthen our position as a leading innovator in diagnostic testing.

"We are also pleased to be included in the PHE national framework, which allows PHE and NHS hospitals to purchase our accredited products without the need for direct contract awards. We look forward to the opportunity to expand our support of diagnostic testing in the UK through our established infrastructure and building a long-term future in this important market, as well as in international markets as we continue to invest in our direct commercial operations."

Expansion of the PathFlow® LFT portfolio

PathFlow® SARS-CoV-2 IgG is a professional use LFT for the detection of SARS-CoV-2 IgG antibodies, launched as a CE-IVD on 31 March 2021. The test provides a rapid turnaround time of results from ten minutes and has demonstrated sensitivity of 98% and specificity of 99% in validation studies.

PathFlow® SARS-CoV-2 SMART IgG is a next generation LFT to detect and, importantly, differentiate between IgG antibodies. The test is expected to assist clinicians in understanding the impact of immunisation programmes, as well as the levels of immunity derived from infection by the virus. The Company now expects to launch this test as a CE-IVD in Q3 2021.

PathFlow® SARS-CoV-2 Antigen is a professional and home use LFT for the detection of SARS-CoV-2 antigens using non-invasive anterior nasal swab samples to provide a result in approximately 15 minutes. Novacyt has been working with a partner to develop this test, which is able to detect the virus regardless of current known mutations. The Company intends to launch the test as CE-IVD before the end of Q2 2021 and expects it to complement Novacyt's established position in COVID-19 PCR testing. As the market for COVID-19 testing continues to develop, the Directors believe this product could add significant revenues for Novacyt.

Expansion of the genesig® COVID-19 PCR portfolio

Following an emerging need in some countries, Novacyt has launched a CE-IVD genesig® COVID-19 three-gene target test for use with nasopharyngeal, oropharyngeal and saliva sample types. This key extension to the genesig® COVID-19 portfolio, alongside the one-gene and two-gene tests, is expected to be critical for use in airport test and release programmes to and from certain countries.

Expansion of the PROmate™ PCR portfolio

PROmate™ remains the only direct-to-PCR assay approved by the UK's Technology Validation Group and enables near-to-patient testing with results in under 90 minutes. The current CE-IVD PROmate™ COVID-19 test identifies the SARS-CoV-2 ORF1ab gene. Due to an emerging need in some countries, the Company expects to launch a second CE-IVD PROmate™ COVID-19 test in May 2021 to identify both the SARS-CoV-2 ORF1ab gene and M gene.

In addition, Novacyt has launched PROmate™ SARS-CoV-2 E484K, a research-use-only (RUO) test to identify this key mutation, with a CE-IVD planned subject to demand. E484K is a mutation found in all current VOC and has been associated with immune evasion and reduction of vaccine efficacy.

Expansion of the SNPsig® PCR genotyping portfolio

In addition to Novacyt's recently launched CE-IVD assay panel, VariPLEX™, the Company has eight RUO assays, which it believes is the most complete variant detection portfolio currently available to address the globally prevalent variants of SARS-CoV-2.

An RUO assay to detect a new variant originally identified in India is expected to be launched in the next week and reinforces Novacyt's leadership in responding to an urgent public health need and market requirements. (Full detail on the SNPsig® portfolio can be found below.)

UK operational update

Novacyt has invested significantly in supporting the UK market during the past 12 months and now has over 50 field specialists servicing the NHS across England, Wales, Scotland and Northern Ireland. In addition, Primerdesign and Microgen Bioproducts, Novacyt's wholly owned subsidiaries, have been included in the National Microbiology Framework for Diagnostic Goods and Services (Lot 1) published by PHE for a full range of clinical products, including tests within the Company's accredited portfolio.

The successful inclusion of Primerdesign and Microgen Bioproducts in the PHE National Framework Agreement, coupled with the Company's investment in its commercial infrastructure to deliver new products and establish a direct sales force, means Novacyt is well positioned to develop a long-term commercial position in the UK market.

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About the SNPsig® portfolio

The table below contains details on Novacyt's SNPsig® portfolio of products, which have been launched to date or are due to launch imminently. Novacyt's bioinformatics surveillance group remains highly vigilant and, as significant new mutations are identified, these will be added to the SNPsig® portfolio.

Assay Type	Detection Profile
SNPsig® VariPLEX™ SARS-CoV-2	20I/501Y.V1, 20H/501Y.V2, 20J/501Y.V3, 20C/S.452R, N501Y, E484K
SNPsig® SARS-CoV-2 (20I/501Y.V1)	20I/501Y.V1 (UK)
SNPsig® SARS-CoV-2 (20H/501Y.V2)	20H/501Y.V2 (SA)

SNPsig® SARS-CoV-2 (20J/501Y.V3)	20J/501Y.V3 (Brazil)
SNPsig® SARS-CoV-2 (20B/S.484K)	20B/S.484K (Brazil)
SNPsig® SARS-CoV-2 (N501Y)	Variants with the N501Y mutation (UK, SA & Brazil)
SNPsig® SARS-CoV-2 (E484K)	Variants with the E484K mutation
SNPsig® SARS-CoV-2 (L452R)	Variants with the L452R mutation
SNPsig® SARS-CoV-2 (VUI-21APR-01) *	VUI-21APR-01 (India)
SNPsig® SARS-CoV-2 (VUI-21MAR-02) *	VUI-21MAR-02 (Brazil)

*in development

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 offers microbiology, haematology and serology products with a focus in respiratory and transplantation markets.

For more information please refer to the website: www.novacyt.com

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