Correction: Research and Development Update

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Novacyt S.A.
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("Novacyt", the "Company" or the "Group")

Correction: Research and Development Update

This is a correction to the Research and Development Update announcement published at 7:00am on 24 February 2021 (RNS number 1141Q) which has been amended with the following underlined additions to make it consistent with the French announcement released on Euronext at 8:00am CET on 24 February 2021.

Under the subtitle 'Launch of CE Mark COVID-HT Direct'

· Novacyt announces the launch of its next generation high-throughput PCR test for COVID-19 (COVID-HT Direct), which has been CE Mark approved using independent validated data.

· The new COVID-HT Direct uses pharyngeal swabs collected in viral transport media (without guanidine) and saline

Under the subtitle 'Successful completion and publication of TVG validation of PROmate™'

· This TVG accreditation supports the use of the q16/q32 and PROmate™ system in a near patient setting, and its current deployment across the NHS and to international markets.

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

Paris, France and Camberley, UK - 24 February 2021 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, announces an update on the progress of its near-term research and development programmes, including the expansion of its product portfolio, clinical trial activity and the publication of independent validations of the Company's COVID-19 tests.

In parallel with the current focus of continuing to maximize the opportunity for COVID-19 testing, the Company is

also continuing to build on its strategy for delivering a sustainable, long-term diagnostics business. Novacyt intends to present these plans during Q2 2021.

The expansion of the Company's COVID-19 portfolio continues to address the rapidly evolving diagnostics market:

· Expansion of the SNPsig® portfolio to detect new SARS-CoV-2 variants of concern, including a specific variant prevalent in the US

· Launch of CE Mark COVID-HT Direct, a next generation direct-to-PCR SARS-CoV-2 test for high-throughput laboratories

· Development of the COVID-19 antibody lateral flow test

· Development of the loop-mediated isothermal amplification COVID-19 test

· Development of an innovative assay panel for the detection of aspergillus, a respiratory fungal infection associated with co-infection risk in patients with COVID-19

· Development of a two-gene target PROmate™ test to address markets employing this testing approach

The Company continues to support clinical research teams undertaking clinical trials in the global COVID-19 testing market:

· Queen Mary University of London has successfully completed the clinical trial of rapid testing in care homes using the Company's rapid PCR system

· The variant diagnostic surveillance study has initiated in the UK, US, and Latin America

Novacyt's COVID-19 portfolio continues to be supported by independent validations and accreditations:

· The DHSC Technical Validation Group reported the successful completion of the in-service validation of PROmate™

· AstraZeneca reported the successful implementation of saliva testing of staff using Novacyt's genesig® COVID-19 assay

Expansion of the SNPsig® portfolio

With the rapid emergence of significant SARS-CoV-2 variants, the Company has expanded the polymerase chain reaction (PCR) genotyping portfolio, SNPsig®, announced on 2 February 2021, to incorporate the detection of two new variants of concern (VOC), first identified in Bristol (202102/02)1 and California (B.1.429/CAL.20C)2. These additions demonstrate the Company's ability to match the rapid evolution of the virus with real-time bio-informatics surveillance and accelerated product development. The variant diagnostics surveillance study, also announced on 2 February 2021, has initiated in sites in the UK, US and Latin America, enabling scientists and healthcare professionals in the field to determine the incidence of the principal VOC in their populations and to formulate strategies for containment and / or specific patient management.

Launch of CE Mark COVID-HT Direct

Novacyt announces the launch of its next generation high-throughput PCR test for COVID-19 (COVID-HT Direct), which has been CE Mark approved using independent validated data. This follows the launch of the Company's first high-throughput PCR test for COVID-19 (COVID-HT) in June 2020. The new test eliminates the need for automated extraction systems in a high-volume PCR laboratory, reducing processing time, cost and labour of testing by up to 30%. The new COVID-HT Direct uses pharyngeal swabs collected in viral transport media (without guanidine) and saline. COVID-HT Direct is already in use at one of the UK's Lighthouse laboratories and is being validated for use with private high-throughput PCR laboratory partners.

Development of an antibody lateral flow test for COVID-19

The Company continues to work on developing an IgG antibody lateral flow test (LFT) for use as a rapid antibody test for professional use. An LFT is an easy-to-use diagnostic device used to confirm the presence or absence of a pathogen or biomarker and takes approximately 10-20 minutes or less to provide a result.

The Company expects to launch its LFT in Q2 2021, slightly later than planned as it has taken the strategic decision to develop a next generation of LFT to detect the neutralizing antibodies generated by successful immunisation and, therefore, to assist in monitoring the effectiveness of future vaccines 3. The Company believes this exemplifies how it can extend the revenue horizon for COVID-19 as the demand for testing continues to evolve.

Development of a loop-mediated isothermal amplification COVID-19 test

Further to the announcement on 16 November 2020, the Company has completed early studies using its loop-mediated isothermal amplification (LAMP) technology with its q16 and q32 instrument platforms and open LAMP platforms and demonstrated encouraging initial results. Novacyt continues to evaluate the ongoing opportunity for LAMP testing and will launch its technology subject to demand.

Development of a new test panel to detect aspergillosis fungal infections

Aspergillosis is an infection caused by aspergillus fungus common in immune compromised patients4, and more recently has been associated with co-infection in patients with SARS-CoV-25 infections and COVID-19-associated pulmonary aspergillosis6. The infection is associated with long-term ventilation of patients. Outside of SARS-CoV-2 infections, aspergillosis also remains a potentially serious respiratory infection, affecting ~5 million patients worldwide7.

Novacyt's new multiplex PCR assay panel will detect all five major aspergillus sub-types and will run on the Company's q32 instruments, as well as open platforms. Novacyt expects to begin validation studies soon, with the potential to launch during H2 2021.

Once launched, the new assay panel will be the second product in the Company's COVID-19+ portfolio, following the launch of the Winterplex™ multiplex assay panel in August 2020. This launch is also in line with Novacyt's strategy to expand its portfolio of clinical use, respiratory diagnostic products.

Development of a two-gene target PROmate™ test

Following the early success of the PROmate™ test to improve workflow efficiency when used with the Company's

q16 and q32 instrument platforms, Novacyt is developing a two-gene version of this test to support those markets and use cases where a two-gene target test is required. The same operational benefits will be available for customers.

Successful completion of clinical trial with Queen Mary University of London

Further to the announcement on 16 November 2020, Queen Mary University of London (QMUL) has completed the clinical trial using the Company's rapid testing platforms for COVID-19 in care homes. Upon completion, over 4,500 samples and subsequent results have been recorded. The data analysis is now underway, and the results are expected to be reported in H2 2021.

Successful completion and publication of TVG validation of PROmate™

As stated in the announcement on 29 January 2021, the UK's in-service validation of the PROmate™ assay using the Company's q16 and q32 instrument platforms was successfully completed in December 2020 and published by the Technology Validation Group (TVG) in January 20218.

The independent study was undertaken at four NHS laboratories with 759 samples, including 242 positive and 517 negative samples. Analysis of the results demonstrated a very high level of sensitivity and specificity, aligning the performance of PROmate™ with the Medicines and Healthcare products Regulatory Agency standard for point-of-care (rapid testing). This TVG accreditation supports the use of the q16/q32 and PROmate™ system in a near patient setting, and its current deployment across the NHS and to international markets. PROmate™ is the only direct-to-PCR assay with TVG validation and reiterates the Group's position at the forefront of PCR technology.

Successful implementation of saliva testing of AstraZeneca staff using the genesig® COVID-19 assay

In early 2020, AstraZeneca set up an internal programme of voluntary SARS-CoV-2 testing for asymptomatic employees in the UK and Sweden using Novacyt's genesig® COVID-19 test. By February 2021, approximately 70,000 SARS-CoV-2 PCR tests had been completed within AstraZeneca's internal global testing centres, of which 54,000 are based on saliva swabs. Following the introduction of saliva testing, adoption by employees increased approximately four-fold and over 90% of 1,062 employees surveyed expressed a preference for the change from the typical oropharyngeal (throat) or nasopharyngeal (nasal) swabs. The study highlights the 90% uptake of saliva testing for asymptomatic patients and the excellent detection rates of 0.33 copies of whole viral genome RNA/µL, sensitivity of ≥95% and 100% specificity.9 These result shows how PCR testing can be used for asymptomatic mass-testing.

Graham Mullis, Group CEO of Novacyt, commented:

"Novacyt remains focused on leveraging its innovative reputation and position in the rapidly changing COVID-19 testing market to continue to deliver value and support clinicians and laboratories in a global setting. Of note, following its launch, our PROmate™ test has been well received by users and opens up new opportunities for rapid PCR testing, including in private testing markets. In addition, we look forward to presenting exciting long-term plans for Novacyt during Q2 this year as we continue to define our strategy for delivering sustainable, long-term growth."

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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 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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3 "Covid: South Africa halts AstraZeneca vaccine rollout over new variant". BBC News. 8 February 2021

4 https://www.cdc.gov/fungal/diseases/aspergillosis/index.html

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6 Salmanton-García J, Sprute R, Stemler J, Bartoletti M, Dupont D, Valerio M, et al. COVID-19-associated pulmonary aspergillosis, March-August 2020. Emerg Infect Dis. 2021 Apr. https://doi.org/10.3201/eid2704.204895

7 Denning DW, Pleuvry A, Cole DC. Global burden of allergic bronchopulmonary aspergillosis with asthma and its complication chronic pulmonary aspergillosis in adults.external icon Med Mycol. 2013 May;51(4):361-70.

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9 Nikki Carter, Maryam Clausen, Rebecca Halpin et al. A novel, automated SARS-CoV-2 saliva PCR test protects a global asymptomatic workforce, 17 February 2021, PREPRINT (Version 1) available at Research Square [https://doi.org/10.21203/rs.3.rs-246781/v1]

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