

# R&D Update

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Novacyt S.A.

16 November 2020

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

## R&D Update

Continued expansion of COVID-19 product portfolio to address unmet market needs

Paris, France and Camberley, UK - 16 November 2020 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, announces an R&D update.

## R&D highlights

- Encouraging interim data from ongoing clinical trial in care homes confirms accuracy of Novacyt's near-patient testing (NPT) system compared to central laboratory testing of COVID-19
- Launch of PROMate™, a new product to improve the workflow efficiency of Novacyt's NPT system for COVID-19 testing
- Development of a loop-mediated isothermal amplification (LAMP) test for COVID-19
- Development of an antibody lateral flow test (LFT) for COVID-19
- Development of a research-use-only (RUO) test for a new strain of COVID-19

Novacyt's near-term focus remains to deliver strong organic revenue growth in the core business, where the Directors believe demand for its products will continue to grow well into 2021 as COVID-19 testing continues. In the medium-term, Novacyt expects to leverage its reputation, market intelligence and relationships developed during the COVID-19 response to commercialise new products, as well as expand its presence in respiratory and transplant clinical diagnostics, to continue to meet significant unmet market needs.

As part of Novacyt's strategy, the Company also continues to invest in developing its IP portfolio to enhance and secure future value and has submitted 15 new patents covering various aspects of its COVID-19 portfolio.

## Clinical trial update using Novacyt's NPT system in care homes

Further to the announcement on 22 July 2020, Queen Mary University of London (QMUL) has completed an interim review of the performance of the Company's innovative near-patient testing (NPT) system in an ongoing study testing for COVID-19 in care homes.

The interim review analysed over 4,000 samples from care home residents and staff, with 98% of the samples using Novacyt's NPT system processed and reported in the same day. The clinical accuracy of Novacyt's NPT system was found to have >99% clinical sensitivity and specificity when compared to a standard central laboratory system. These data demonstrate the reliability and accuracy of Novacyt's NPT system. In addition, mid-nose nasal swabs were found to be effective and well tolerated compared to the more invasive nasopharyngeal swabs.

Further to the announcement of Novacyt's second contract with the UK DHSC on 29 September 2020 for the supply of q16 and q32 instruments and test kits to NHS hospitals, the clinical trial is being expanded into additional settings across the UK where the Company's NPT systems are being deployed.

## Launch of PROMate™

PROMate™ is a new CE Mark approved product designed to further improve the workflow efficiency of COVID-19 testing when used in combination with the Company's q16 and q32 instruments. The reagents involved in the Company's COVID-19 RNA extraction and PCR test products have been repackaged, with some reagents also freeze-dried, to reduce the amount of consumables and the number of steps required, thereby reducing operator complexity and improving cycle times. In addition, PROMate™ uses a viral inactivation methodology validated by Public Health England for potential use outside of laboratory environments.

As Novacyt's NPT system continues to be deployed across the NHS, and globally, this improvement in workflow efficiency for COVID-19 testing is expected to make the system one of the quickest and easiest to use PCR platforms in its class.

Further to the announcement on 15 October 2020 when Novacyt acquired IT-IS International, the Company has significantly increased the manufacturing capability of IT-IS to manage the growing demand for its q16 and q32 instruments. From November 2020, the Company has scaled-up manufacturing capacity for instrument production more than five-fold, with further expansion planned, depending on continued demand.

## Development of a LAMP COVID-19 test

Loop-mediated isothermal amplification (LAMP) technology is a single-tube technique for the amplification of DNA and RNA and is considered a low-cost alternative to detect certain diseases, including COVID-19. Isothermal amplification is carried out at a constant temperature without the need for a thermal cycler, contrasting to PCR amplification, which is carried out with a series of alternating temperature steps or cycles in a thermal cycler.

Novacyt is currently developing a LAMP test for COVID-19, including evaluating the trade-off between cycle time

and test performance. The Company expects to launch the product during Q1 2021 with an expected cycle time of 20 minutes or lower. Novacyt's LAMP offering is designed to be compatible with its q16 and q32 instruments. The Company is also in active discussions with several potential partners who are seeking support to develop, manufacture and supply LAMP tests for their instrument platforms.

#### Development of an antibody lateral flow test for COVID-19

On 29 September 2020, Novacyt announced the launch of its IgG specific antibody test for use in central laboratory testing. The Company is also working 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. The product is expected to launch during Q1 2021 and is expected to take approximately 20 minutes or less to give a result.

#### Development of a RUO test for a new strain of COVID-19

Further to the identification of a mutation of COVID-19 in Danish mink, Novacyt has taken the strategic decision to develop a research-use-only (ROU) PCR test for a specific new strain of the virus. The analysis currently available suggests there are four mutations that have been found in mink. One of the mutations, known as Y453F, is of potential concern to scientists and clinicians as it causes an amino acid change which affects antibody binding. This could have implications for vaccine strategies, which are predicated on stimulating a defined antibody response to the virus<sup>1</sup>.

While it is unknown what, if any, impact the amino acid modification will have on vaccines, Novacyt believes a RUO test could help scientists and clinicians to identify patients that carry the virus with the Y453F mutation. The Company expects to launch this novel test in December 2020. Should a clinical need arise for the diagnostic differentiation of Y453F from other strains of COVID-19 infection, Novacyt will be well positioned to offer this as a clinical use diagnostic product.

<sup>1</sup> [https://files.ssi.dk/Mink-cluster-5-short-report\\_AF02](https://files.ssi.dk/Mink-cluster-5-short-report_AF02)

Graham Mullis, Group CEO of Novacyt, commented:

"Novacyt continues to innovate in its response to the rapidly changing needs of the COVID-19 testing market. In particular, the launch of PROmate™ is expected to further improve the workflow efficiency of our near-patient testing system, enabling reduced operator complexity and faster cycle times for our market leading PCR COVID-19 test. Not only do the additions to the portfolio broaden the Company's ability to support clinicians and laboratories through the pandemic, they also strengthen our position in infectious disease diagnostics as we continue to redefine our R&D pipeline for the next three years, in line with our long-term growth strategy."

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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](http://www.novacyt.com)

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