## **R&D** update

RNS Number: 4589N Novacyt S.A. 30 September 2021 Novacyt S.A. ("Novacyt", the "Company" or the "Group") R&D update Including launch of two new tests to differentiate between COVID-19 and common winter viruses, and between COVID-19 variants Paris, France and Camberley, UK - 30 September 2021 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, announces an R&D update. Highlights · Launch of a new CE Mark Winterplex™ PCR test to diagnose COVID-19, respiratory syncytial virus (RSV) and types of influenza Launch of a new CE Mark Escapeplex™ PCR test to diagnose four key COVID-19 variants · Development of CO-Prep™ to further automate and streamline the workflow process of the Company's nearpatient PROmate® test

genesig® SARS-CoV-2 Winterplex™

· Update on PathFLOW® lateral flow test (LFT) portfolio

As the Northern hemisphere approaches the 2021-2022 flu season, Novacyt has carried out an analysis of recent influenza genome sequences using its specialist bioinformatics surveillance expertise to determine how significant the genetic drift was in the virus from the previous year. Through this analysis, Novacyt detected significant mutations in published sequences of the influenza B (flu B) virus and developed a new Winterplex™ test to address the new flu B strain for the 2021-2022 winter flu season. The new Winterplex™ test combines flu B, three-gene COVID-19, flu A and RSV assays in a single kit to provide clinicians and laboratories with a comprehensive testing solution. The test is designed for use in central laboratories with open PCR platforms.

Following the successful launch of Escapeplex™ as a research-use-only (RUO) test in April 2021, Novacyt has launched a CE Mark version of the test to meet demand for clinical use. Escapeplex™ includes gene targets for four key mutations or Variants of Concern (VoC) of SARS-CoV-2, enabling clinicians and laboratories to detect the most significant virus variants in a single kit. The test identifies four escape mutations known to be associated with the most significant VoCs. Escapeplex™ has been designed to be used in central laboratories with open PCR platforms.

## Development of CO-Prep™

In line with the Company's strategy to build on its capabilities in near-patient testing through improved workflow solutions, Novacyt has codeveloped CO-Prep™, an instrument for sample handling automation. CO-Prep™ has been designed to automate the liquid handling steps of the Company's near-patient PROmate® test. The efficient CO-Prep™ workflow includes a small footprint for use on benchtops or in containment hoods. As a result, CO-Prep™ offers laboratories increased capacity, automation of repetitive manual pipetting, increased accuracy, reduction in intra-sample contamination risk, and time for technicians to concentrate on other work.

The new CO-Prep<sup>™</sup> instrument has received significant interest from customers in advance of the launch next month. PROmate<sup>™</sup> and Co-Prep<sup>™</sup> have currently been designed for testing of COVID-19, but both testing and instrument technologies can be used to target additional diseases in the future.

## PathFLOW® update

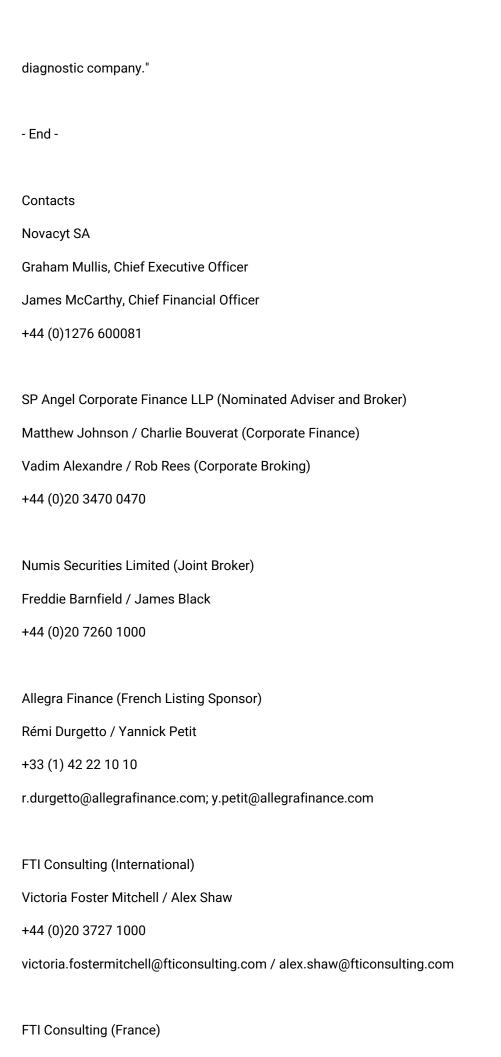
Further to the announcement on 29 June 2021, the Company's confirms there is a delay in the launch of PathFlow® COVID-19 Rapid Antigen, a self-LFT to detect SARS-CoV-2 antigens, previously expected in Q3 2021. This delay is due to increased demand for self-test approvals causing a backlog of tests currently under review by the Company's Notified Body. The Notified Body has communicated a delay of up to six months, therefore, the Company is also evaluating other approved options for a COVID-19 self-LFT.

Further to the announcement on 23 April 2021, Novacyt's PathFlow® SARS-CoV-2 SMART IgG LFT, expected to launch in Q3 2021, is also delayed. This is due to the Company's partner being unable to secure sufficient supplies for Novacyt to launch the test. Novacyt is, therefore, evaluating additional LFT options to detect and differentiate between SARS-CoV-2 IgG antibodies.

Novacyt remains focused on expanding its COVID-19 LFT portfolio, following the launch of its PathFLOW® SARS-CoV-2 antigen and antibody LFTs for professional use earlier this year, to complement the Company's growing polymerase chain reaction (PCR) portfolio.

Graham Mullis, Chief Executive Officer of Novacyt, commented:

"The launch of two new CE Mark tests, Winterplex™ and Escapeplex™, to address the approaching winter flu season in the Northern hemisphere and key mutations of COVID-19 in a single kit, respectively, reinforces Novacyt's ability to address evolving needs in the diagnostics market. Novacyt's continued focus on innovation is demonstrated by the development of CO-Prep™ to provide further workflow solutions for clinicians and laboratories testing for COVID-19. This automated instrument technology can also be leveraged for future disease areas to support the Company's growth beyond COVID-19. 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 global



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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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