

Coronavirus test update

RNS Number : 9622H

Novacyt S.A.

30 March 2020

Novacyt S.A.

("Novacyt" or the "Company")

Coronavirus test update

Sales and manufacturing update

COVID-19 test approved in India and Argentina

Paris, France and Camberley, UK - 30 March 2020 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, is pleased to provide an update regarding the novel coronavirus (COVID-19) test developed by Primerdesign, the Company's molecular diagnostics division based in the UK.

Sales and regulatory update

As of 27 March, Primerdesign has sold and received orders for over £17.8 million (€19.6 million) of its CE-Mark and research use only (RUO) COVID-19 tests. The rate of demand for the test continues to increase, and on 27 March, Primerdesign received its largest single order to date of £1.4 million (€1.5 million) from a new customer in India following emergency use approval of the test on 26 March 2020.

Novacyt is now selling its COVID-19 test to more than 80 countries and the Middle-East is becoming the strongest selling region, with orders of £1.6m (€1.8m) received in less than two weeks. The Company expects to sign further distribution partnerships during the next few weeks in this region and also expects to update on its progress in the US market following Emergency Use Authorization granted by the US Food and Drug Administration announced on 23 March 2020.

Novacyt continues to work with a growing number of hospitals in the UK and is now supplying more than 21 hospitals across the country. The Company also reports that its COVID-19 test is now being used by the Health Service Executive in Ireland and orders for £1.1 million (€1.2 million) tests have been received.

Although Novacyt is unable to predict with any certainty the conversion rate of its ongoing enquiries into orders and so provide meaningful sales guidance, the Directors can confirm that this level of sales will contribute significantly to improved gross margin and profitability for the Group.

On 27 March 2020, Novacyt received approval for the test from the National Administration of Drugs, Foods and Medical Devices (ANMAT) in Argentina.

The Company continues its extensive surveillance program to monitor strain evolution of the SARS-CoV-2 virus and the latest update continues to demonstrate a 100% homology of its COVID-19 test. To date, this means comparing the Company's COVID-19 test to genome sequences from 1,700 known variations of COVID-19. The Directors believe this extensive surveillance and performance homology will continue to allow clinicians to use the test with confidence.

Manufacturing capacity

Further to the announcement on 12 March 2020, Novacyt can confirm its manufacturing partner, located in mainland Europe, is BioType Diagnostic GmbH (BioType). BioType, based in Dresden, Germany, is making excellent progress in scaling-up manufacturing and the first batches of product have been delivered to Primerdesign's Southampton site for final assembly. In addition, the Directors have taken the decision to increase the level of output contracted with BioType, which, combined with the capacity from Southampton, will enable the Company to produce more than 4 million tests per month.

Whilst the Company looks forward to receiving the first batches of certain product associated with its COVID-19 test from its UK-based manufacturing partner, YourGene Health Plc, Novacyt is also in advanced discussions with an additional UK-based third-party manufacturer to further expand manufacturing capacity.

The Company has committed to purchasing additional raw materials to produce a total of 18 million COVID-19 tests and, with demand growing at an increasing rate, this will continue to be reviewed during the next few weeks.

Graham Mullis, Chief Executive Officer of Novacyt, commented:

"We continue to report unprecedented demand for our COVID-19 test as the rate of growth in orders increases each week and continues to exceed our expectations. As a result, and despite our best efforts to ensure we are fully prepared to meet demand, the rate of sales growth is beginning to be restricted by our ability to scale-up manufacturing as quickly as we would like. This, therefore, remains an immediate priority for the Company and it is our objective to make as many tests available to as many clinicians around the world as quickly as possible. We are very pleased with how our manufacturing partners, BioType and Yourgene, are supporting Novacyt during this time and we continue to evaluate additional capacity enhancing options to address the global demand for our COVID-19 test. Again, I would like to thank all of our employees and suppliers for their ongoing hard work and support during this pandemic."

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014.

- End -

Contacts

Novacyt SA

Graham Mullis, Chief Executive Officer

Anthony Dyer, Chief Financial Officer

+44 (0)1276 600081

SP Angel Corporate Finance LLP (Nominated Adviser and Broker)

Matthew Johnson / Charlie Bouverat (Corporate Finance)

Vadim Alexandre / Rob Rees (Corporate Broking)

+44 (0)20 3470 0470

FTI Consulting (International)

Victoria Foster Mitchell / Mary Whittow

+44 (0)20 3727 1000

victoria.fostermitchell@fticonsulting.com / mary.whittow@fticonsulting.com

FTI Consulting (France)

Arnaud de Cheffontaines

+33 (0)147 03 69 47

arnaud.decheffontaines@fticonsulting.com

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

About COVID-19

Researchers at the Chinese Centre for Disease Control and Prevention and their collaborators have sequenced the 2019 novel coronavirus (COVID-19) pathogen from patient samples and have found it to be genetically distinct from the severe acute respiratory syndrome (SARS) virus that caused an epidemic in 2002 and 2003, as well as from the Middle East respiratory syndrome (MERS) virus that was detected in 2012.

About BioType Diagnostic GmbH

Biotype GmbH is a molecular diagnostics company located in Dresden, Germany, specialising in the development, production and distribution of molecular diagnostic solutions for the detection and quantification of RNA and DNA markers. The assays support diagnosis and therapy in oncology, haemato-oncology, dermatology and infectious diseases. All tests run either on commercial qPCR devices or on the proprietary Modaplex system, which enables the simultaneous and cost-effective detection of up to 50 different DNA/RNA targets within a few hours.

With more than 20 years of experience Biotype, offers development and production services of customised test kits for third parties, such as pharmaceutical, diagnostic and biotech companies. Biotype's certified contract development & manufacturing service covers all challenges from the idea up to the realisation of a marketable product. The company offers production under clean room conditions and can adjust to diverse manufacturing requests by providing scalable production capabilities.

This information is provided by RNS, the news service of the London Stock Exchange. RNS is approved by the Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact rns@lseg.com or visit www.rns.com.

END

UPDDBGDXRUDDGGC