IVDR accreditation

RNS Number : 5085I
Novacyt S.A.
17 October 2024

Novacyt S.A.

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

IVDR accreditation for Yourgene® Cystic Fibrosis *Base* assay

Paris, France, Eastleigh and Manchester, UK - 17 October 2024 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international molecular diagnostics company with a broad portfolio of integrated technologies and services, announces that it has received accreditation under the new EU requirements of the *In Vitro* Diagnostic Regulation ("IVDR") for the Yourgene® Cystic Fibrosis *Base* assay. The Yourgene® Cystic Fibrosis *Base* assay is a Class C *in vitro* medical device under IVDR and is intended for use by healthcare professionals within a molecular laboratory environment.

IVDR ensures that the Yourgene® Cystic Fibrosis *Base* test, which is manufactured for sale in the EU, is assessed against stringent quality, safety and performance requirements. Manufacturers must provide considerable evidence of scientific validity, as well as data demonstrating analytical and clinical performance of the tests. The Yourgene® Cystic Fibrosis *Base* test was assessed by British Standards Institution (BSI), an independent conformity assessment body, and was shown to conform to the new regulations.

Cystic Fibrosis ("CF") has become the most common life-shortening hereditary genetic condition affecting 1 in 2,500 live births in Caucasians. In the UK, all newborns are screened for CF as part of the newborn blood spot test. The test is performed within the first three days of a baby's life and involves pricking the baby's heel and collecting a few drops of blood on a card. The blood is then tested for CF and other rare conditions. The Yourgene® Cystic Fibrosis *Base* assay uses Amplification-Refractory Mutation System technology and genetic analysers to detect point mutations, insertions or deletions in DNA. The assay is designed with all clinically relevant diagnostic scenarios in mind such as carrier screening, newborn screening and male factor infertility testing.

The Yourgene® Cystic Fibrosis *Base* test, part of Yourgene's Reproductive Health portfolio, is used to identify patients with any of the 50 most common CF mutations in the European population.

Lyn Rees, CEO of Novacyt, commented: "*This is the second product within the now enlarged Novacyt product portfolio to conform to the new EU IVDR regulations and is one of the first IVDR CF tests on the market. Conformity with IVDR provides clinicians and patients with additional confidence in the high-quality and accuracy of our test which is increasingly becoming an essential test in the detection and diagnosis of CF.*

"CF testing is prevalent globally and there has recently been an increase in some regions due to increased reimbursement. This includes Australia where the Australian government have introduced a nationwide reimbursement pathway that enables all eligible Australians to receive CF screening either prior to, or early in pregnancy. With increasing momentum in this market, the IVDR accreditation only further validates the quality of our test within the EU and beyond."

Contacts

Novacyt SA	https://novacyt.com/investors
Lyn Rees, Chief Executive Officer	**Via Walbrook PR**
Steve Gibson, Chief Financial Officer	
SP Angel Corporate Finance LLP (Nominated Adviser and Broker)	+44 (0)20 3470 0470
Matthew Johnson / Charlie Bouverat (Corporate Finance) Vadim Alexandre / Rob Rees (Corporate Broking)	
Deutsche Numis (Joint Broker)	+44 (0)20 7260 1000
Freddie Barnfield / Duncan Monteith / Michael Palser	
Allegra Finance (French Listing Sponsor) Rémi Durgetto / Yannick Petit	+33 (1) 42 22 10 10 r.durgetto@allegrafinance.com / y.petit@allegrafinance.com
Walbrook PR (Financial PR & IR) Stephanie Cuthbert / Paul McManus / Phillip Marriage / Alice Woodings	+44 (0)20 7933 8780 or novacyt@walbrookpr.com +44 (0)7796 794 663 / +44 (0)7980 541 893 +44 (0)7867 984 082 / +44 (0)7407 804 654

About Novacyt Group (www.novacyt.com)

Novacyt is an international molecular diagnostics company providing a broad portfolio of integrated technologies

and services, primarily focused on the delivery of genomic medicine. The Company develops, manufactures, and commercialises a range of molecular assays and instrumentation to deliver workflows and services that enable seamless end-to-end solutions from sample to result across multiple sectors including human health, animal health and environmental.

The Company is divided into three business segments:

Clinical	Broad portfolio of human clinical *in vitro* diagnostic products, workflows and services focused on three therapeutic areas: · Reproductive Health: NIPT, Cystic Fibrosis and other rapid aneuploidy tests · Precision Medicine: DPYD genotyping assay · Infectious Diseases: Winterplex, multiplex winter respiratory PCR panel
Instrumentation	Portfolio of next generation size selection DNA sample preparation platforms and rapid PCR machines, including: · Ranger® Technology: automated DNA sample preparation and target enrichment technology · genesig q16 and q32 real-time quantitative PCR (qPCR) instruments
Research Use Only	Range of services for the life sciences industry: · Design, manufacture, and supply of high-performance qPCR assays and workflows for use in human health, agriculture, veterinary and environmental, to support global health organisations and the research industry · Pharmaceutical research services: whole genome sequencing (WGS) / whole exome sequencing (WES)

Novacyt is headquartered in Vélizy-Villacoublay in France with offices in the UK (in Eastleigh and Manchester), Singapore, the US and Canada and has a commercial presence in over 65 countries. The Company is listed on the London Stock Exchange's AIM market ("NCYT") and on the Paris Stock Exchange Euronext Growth ("ALNOV").

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

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.RNS may use your IP address to confirm compliance with the terms and conditions, to analyse how you engage with the information contained in this communication, and to share such analysis on an anonymised basis with others as part of our commercial services. For further information about how RNS and the London Stock Exchange use the personal data you provide us, please see our Privacy Policy.

END

MSCUNORRSKURAUA