Novacyt launches two new molecular diagnostic kits

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molecular diagnostic kits

First of an expanding menu of tests for monitoring post-transplantation and immunosuppressed patients

Paris, France and Camberley, UK - 21 December 2018 - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, today announces the launch of its next CE-Marked approved molecular products, the genesig® Real-Time PCR BK virus (BKV) Kit (CE) and genesig® Real-Time PCR Epstein-Barr Virus (EBV) Kit (CE). These clinical products follow the launch of a Zika assay in the second half of 2017 and are the first of an expanding menu of molecular diagnostic tests for monitoring post-transplantation and immunosuppressed patients.

The new molecular kits have been developed to provide quantitative detection of viral DNA extracted from blood plasma and urine (BKV kit), or blood plasma and whole blood (EBV kit) from immunocompromised patients. The kits have been designed to run using the Roche LightCycler 480 PCR instrument. Novacyt believes there are over 2,000 LightCycler instruments installed worldwide and the availability of these kits will mean clinical labs running these PCR instruments will now be able to benefit from running these assays. Quantification standards in the kits are calibrated against the First World Health Organization International Standards for Virus Nucleic Acid Amplification Techniques (NIBSC code 14/212), producing strong levels of sensitivity and specificity performance as well as reproducibility.

The global transplant diagnostic and monitoring market is expected to grow at a compound annual growth rate (CAGR) of 10% due to a worldwide rise in the numbers of transplant procedures and is expected to be worth $1.0 Billion by 2022 (source: Allied Market Research Report Transplant Diagnostics Market). Certain pathogens have been associated with increased risk of organ rejection and physicians monitor patients to ensure that rejection risk is minimised. Another important post-transplant pathogen test is Cytomegalovirus (CMV) and Novacyt has already initiated development of a CMV assay to work alongside the BKV/EBV assays, which is targeted to be launched during 2019.

Background to BKV

BKV is a polyomavirus and which can cause disease in humans. BKV primary infection usually occurs in childhood leading to symptoms similar to a common cold followed by lifelong latent infection. BKV causes disease during

transplantation, including BKV-associated nephropathy in kidney transplantation, which leads to renal injury and graft loss. BKV also leads to haemorrhagic cystitis in hematopoietic cell transplantation.

Background to EBV

EBV is a gamma herpesvirus, and like BKV can cause disease in humans. EBV primary infection usually occurs in childhood leading to asymptomatic viremia followed by lifelong latent infection, while later infection can lead to mononucleosis. EBV has oncogenic potential and is associated with a range of cancers, including Post-Transplant Lymphoproliferative disorder in post-transplant recipients.

To prevent diseases caused by both BKV and EBV, there is increasing demand for monitoring DNAemia after transplantation and in patients undergoing immunosuppression.

Graham Mullis, Group CEO of Novacyt, commented:

"Investment in targeted R&D in our molecular diagnostics business is a key strategic growth driver for Novacyt and I am very pleased to announce the launch of these two new clinical diagnostic kits, which reinforce Novacyt's ability to develop CE-IVD products. We also look forward to expanding our pipeline in this fast-growing area to include a CMV test during 2019, further increasing our portfolio of CE-IVD tests."

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About Novacyt Group

The Novacyt Group is a rapidly growing, international diagnostics group with a growing portfolio of cancer and infectious disease products and services. Through its proprietary technology platform, NOVAPrep®, and molecular platform, genesig®, Novacyt is able to provide an extensive range of oncology and infectious disease diagnostic products across an extensive international distributor network. The Group has diversified sales from diagnostic reagents used in oncology, microbiology, haematology and serology markets, and its global customers and partners include major corporates.

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

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