

## **Novacyt provides an R&D update on its initial molecular products pipeline**

**Paris, France and Cambridge, UK – 5th September 2016** – Novacyt (ALTERNEXT: ALNOV), an international clinically focused diagnostics company, today provides a Research and Development (R&D) update following the completion of the acquisition of Primerdesign in May 2016. The integration of Primerdesign is progressing well, in line with the strategic objectives and management expectations defined at the time of the acquisition. Novacyt has now identified its initial molecular diagnostic targets for the clinical testing market, with the first assay expected to be launched in H1 2017.

Novacyt has committed to developing and marketing a portfolio of CE market clinical diagnostic products from Primerdesign's extensive non-clinical catalogue. The Company has selected the following six infectious disease assays for development and commercialisation: a broad spectrum human papilloma virus (HPV); Zika virus and a multiplex assay that differentiates between the Zika, dengue and chikungunya viruses; aspergillus and pneumocystis. The company intends to commercialise these assays through Novacyt's existing sales channels.

### **Initial Pipeline**

#### ***Broad spectrum HPV molecular assay to identify the 14 higher risk subtypes of the HPV infection***

The global PAP and HPV market is forecast to grow at a 6.6% CAGR<sup>1</sup>, reaching \$4.5bn by 2020. The HPV market alone is forecast to reach \$512m by 2020, driven by a growing and aging population, increased awareness about HPV and linked diseases as well as systematic government programmes across the globe. The new Primerdesign HPV high risk assay will complement Novacyt's offering in this exciting market. The test will be available in Q2 2017 for research use on open molecular platforms and subsequently as a CE marked assay on the Group's q16 molecular platform.

#### ***Conversion of the successful research use only ("RUO") Zika assay to a clinically approved test***

Adoption of Primerdesign's Zika assay around the world as a RUO test has been strong so far this year particularly in Brazil, USA and Korea. Novacyt plans to complete the CE-IVD submission for the assay by early 2017 which will significantly open up the clinical market opportunity for the Company. In addition, Novacyt is working with a large US hospital to generate the clinical data necessary for submitting an application to the US Food and Drug Administration (FDA) for Emergency Use of the Zika assay. Novacyt anticipate this submission will be during Q4 2016.

#### ***Multiplex test differentiating between three mosquito borne diseases***

Primerdesign has already developed a single tube test for three mosquito borne diseases, Zika, dengue and chikungunya viruses, which is already sold under a RUO label in Brazil, USA, Costa Rica, and several Southeast Asian territories. Clinical testing in Brazil has gone extremely well, with clinical validation for CE-IVD accreditation of this assay to be initiated shortly. There is high demand

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<sup>1</sup> Market report *HPV Testing & Pap Test Market* by MarketsAndMarkets

for simultaneous detection of these three tropical diseases, which present a similar clinical symptomology which cannot be readily distinguished by antibody based tests.

***Next generation aspergillus and pneumocystis assays, providing faster and more sensitive molecular diagnostics for life threatening fungal infections***

Reduced time to treatment with a higher sensitivity test should improve patient outcomes for the more than 10 million patients each year at risk of life threatening fungal infections. These next generation assays are being developed to offer clinicians significant performance improvements over the Company's current fungal products and are expected to launch in H2 2017.

**Graham Mullis, Group CEO of Novacyt, commented:**

*"We are pleased with the progress of the integration of Primerdesign and the opportunities we have identified, in particular the pipeline and commercialisation synergies within our enlarged Group. The six initial product candidates demonstrate these advantages, allowing us to accelerate product development by leveraging the combined expertise across the Group. The initial assays identified, which we expect to launch during the next 18-24 months, all address significant and high growth opportunities in market segments that the Group is currently focused in with its existing sales channels."*

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**About Novacyt Group**

**The Novacyt Group is a leader in the field of cellular diagnostics with a growing portfolio of clinically focused cancer and infectious disease products and services. Through its proprietary technology platform NOVAPREP®, q16 molecular platform and strong international network Novacyt is able to provide an extensive range of oncology and infectious disease diagnostic products. 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](http://www.novacyt.com)**

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