

## **NOVAprep® Regulatory Update in US and China Expands Commercial Reach**

**Paris, France and Cambridge, UK – 23rd February 2017** – Novacyt (ALTERNEXT: ALNOV), an international specialist in clinical diagnostics, today announces a regulatory update for its next generation NOVAprep® technology platform in the US and China.

### **US FDA Market**

Novacyt has successfully registered its NOVAprep® HQ+ Orange vial as a US Food and Drug Administration (FDA) Class I device allowing the NOVAprep® vial to be purchased by providers who can qualify the NOVAprep® vial for cytology or molecular use in the US market. The global Pap smear market was estimated at \$3.4 billion\* in 2016 and the US market, the largest within this is valued at over \$1.7 billion. The molecular HPV testing market in the US is estimated at \$365 million. The Company will now seek to appoint an appropriate commercialisation partner for its unique and proprietary NOVAprep® vial and media system.

### **China**

Novacyt has received CFDA (China Food and Drug Administration) approval for the NOVAprep® system for non-gynaecological cancer testing in China. This is in addition to the CFDA approval, given in February 2015, for NOVAprep® use in cervical cancer screening. This approval means Novacyt, through its direct subsidiary in China, can immediately market the NOVAprep® system in other cancer areas.

Cancer incidence and mortality have been increasing in China, making cancer the leading cause of death since 2010. There is an estimated 4.3 million\*\* new cases of cancer each year in China and, unlike many developed countries, the trends for many cancers are increasing. In women the trend in the most common cancers standardised for each age group had significant upwards trend for colon, breast, cervical, thyroid and lung cancers.

China is the fastest growing market for cervical cancer screening today and by 2020 it is expected to be significantly larger than the US market, becoming the number one market for liquid based cytology screening for the disease. There are estimated to be 60 million cervical cancer screening tests performed annually in China today and by 2020 this could grow to 150 million cervical cancer screening tests per year.

These recent registrations are in addition to the approvals gained last year for NOVAprep® from markets including Australia, Philippines, Qatar, Hong-Kong and Vietnam. Novacyt is waiting for imminent approvals in Thailand and Saudi Arabia and various countries in South America and the Company is committed to continued regulatory expansion in order to commercialise the NOVAprep® technology.

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

"I am delighted with the continued progress we are making in commercialising our proprietary next generation NOVAprep® platform. These regulatory approvals expand the marketing and distribution opportunities for the NOVAprep® platform in cervical cancer screening, which is the largest, and in certain markets, one of the fastest growing cancer screening markets.

The additional non-gynaecological approval in China for NOVAprep® brings the technology to multiple new cancer markets and reinforces our direct sales investment in China, which is already giving substantial growth of 100%+ in 2016 and is expected to deliver more in 2017. We reported strong 100%+ growth across the Asia Pacific region in 2016 and I look forward to updating our shareholders further with the progress we are making in the region during 2017.”

\* Transparency Market Research.

\*\* CA Cancer J Clin 2016; 66:115-132.

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### About Novacyt Group

**The Novacyt Group is a leader in the field of cellular diagnostics 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](http://www.novacyt.com)

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