Advanced Molecular Diagnostic Systems

1 Dalmore Drive,
Scoresby,
Victoria 3179
AUSTRALIA
T: +61 (0)3 9763-1287
F: +61 (0)3 9763-2817
www.generabiosystems.com

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ASX Announcement – GENERA BIOSYSTEMS LIMITED (ASX:GBI)
HEALTH CANADA APPROVAL OF HPV TESTING AS PRIMARY CERVICAL CANCER SCREENING TOOL

Genera Biosystems Limited ('Genera') is pleased to draw the market's attention to the latest development in a clear global trend to HPV being used as the primary screen for cervical cancer screening. Last week Health Canada announced that it has approved the Roche cobas® 4800 HPV (Human Papillomavirus) Test for use as a first-line primary screening test for cervical cancer in women 25 and older.

This follows an announcement on 24 April, 2014 by the US FDA that it approved the first FDA-approved HPV DNA test for women 25 and older that can be used alone to help a health care professional assess the need for a woman to undergo additional diagnostic testing for cervical cancer.

A spokesman for Roche announced that they would seek to partner with healthcare professionals and authorities to redefine and adapt current practice guidelines to encourage clinicians to incorporate these new HPV tests in their patient protocols.

The cobas® 4800 HPV Test provides both pooled high-risk HPV DNA results and individual detection of HPV 16 and HPV 18, the two types responsible for about 70 percent of cervical cancer. Health Canada's decision to approve the expanded use for the cobas® 4800 HPV Test was based on results from the landmark ATHENA trial, which enrolled more than 47,000 women. The study demonstrated that one in four women who are HPV 16 positive will have cervical disease within three years and that nearly 1 in 7 women with normal Pap cytology who were HPV 16 positive actually had high-grade cervical disease that was missed by cytology.

Alongside a well-designed clinical study the ability of the Roche cobas HPV test to simultaneously genotype HPV 16 and 18 was a key determinant in Health Canada's primary screening approval decision.

Like the Roche HPV test, Genera's PapType™ HPV test simultaneously genotypes high risk HPV types but goes further by genotyping 14 high risk types. While HPV types 16 and 18 account for approximately 70% of cervical cancer cases Genera believes that the incorporation of simultaneously genotyping of 14 high risk HPV types, which cause 99.7% of cases, has the

potential to substantially increase specificity of an HPV test, particularly when utilised within a long-term screening program.

With the support of the New Mexico HPV Pap Registry Genera plans to generate meaningful additional clinical data for its PapType™ HPV test in a 60,000 patient screening population. Further, PapType™ will be also be assessed in the Predictors 3 clinical screening study (a 6,000 patient screening population study) by the Wolfson Institute to confirm the potential superior specificity of Genera's test versus the Roche cobas HPV test and others.

The Health Canada decision to approve the cobas HPV test follows a comprehensive recommendation by the Australian Medical Services Advisory Committee (MSAC) on 28 April 2014 to recommend to the Australian Government that the HPV test should replace the current Pap smear. The MSAC recommendation was based upon a long term evaluation that suggested improved cost and effectiveness outcomes could be achieved within the National Cervical Screening Program in Australia, by primary HPV screening with partial genotyping.

MSAC has recommended the adoption of a 5 yearly cervical screening program using a primary HPV test with partial HPV genotyping and reflex liquid-based cytology (LBC) triage.

According to MSAC with the proposed extension of the screening interval from 2 to 5 years, under conservative HPV test assumptions, strategies involving primary HPV screening with partial genotyping would result in a decrease in the average lifetime number of screening or follow up tests per woman in the population, by 45 to 51% compared to current practice.

Lou Panaccio Executive Chairman of Genera said, "Roche's submission for a screening approval of its cobas HPV test accords with the view formed by Genera many years ago which led to the development of our PapType™ HPV test and its protection through a robust portfolio of patents, many of which have been granted in the past few years with coverage extending to 2025 and beyond."

Genera's newly developed *solid phase* version of its PapType™ HPV test appears uniquely positioned. The Predictors 2 clinical study samples run at the Wolfson Institute of Preventative Medicine (London) demonstrated that the PapType™ HPV test has comparable sensitivity to all other commercially available HPV tests – including the Roche cobas HPV test – but is the only test capable of simultaneously genotyping 14 high risk types delivering higher specificity.

Mr Panaccio added, "The recent decisions by government agencies in relation to the cobas HPV test bodes well for Genera and to a certain extent reinforces to us why we have been able to secure strong interest in our current formal process being run by our advisor. Robust HPV tests with the ability to simultaneously genotype are becoming front and centre for many companies currently or wishing to be involved in the HPV testing field in a credible manner.

The global HPV testing market represents a US$2 billion per annum market opportunity as global healthcare agencies adopt HPV testing as the front line screening tool in the fight against cervical cancer.

Genera's other MDx test developed to date RTI-plex™ is a 17-plex assay that targets 12 viral and 3 bacterial respiratory pathogens and sub-types. This multiplexed test is a very sensitive detection system that reports both RNA and DNA analytes.

RTI-plex™ was independently trialled and validated in a ~2100 patient study in conjunction with Sonic Healthcare whilst also completing a ~600 patient study with Healthscope Pathology. Results from these studies have demonstrated a greater than 90% concordance rate with currently used Real Time PCR tests whilst reducing workloads by approximately 70% due to the multiplexing, offering quite compelling economics for a pathology laboratory in adopting RTI-plex™ .

Genera is currently working through a number of options in relation to its formal process as initially announced to ASX in its 2014 half year results release and currently has a view to being in a position to make an announcement in relation to the outcome of the process prior to the end of June 2014.

This process may result in the company entering into a partnering agreement incorporating an associated capital injection including but not limited to a material change in the current composition of Genera's share register or otherwise potentially a change of control event.

For further information please contact:

Mr Lou Panaccio
Executive Chairman
Genera Biosystems Limited
T: +61 (0)3 9763 1287
E: Lou.Panaccio@generabiosystems.com

About Genera Biosystems: Genera Biosystems Limited ("GBI") is an Australian Stock Exchange listed molecular diagnostics company, which develops, manufactures and distributes advanced PCR molecular diagnostics tests. GBI has successfully developed two products to date, PapType™ and RTI-Plex™, with several additional products in the company's development pipeline. Genera manufactures these products in its Therapeutics Goods Administration (TGA) certified manufacturing facility in Scoresby, Victoria, Australia.