Advanced Molecular Diagnostic Systems

ASX Release

Major clinical study confirms Genera Biosystems' PapType™ Human Papillomavirus detection test outperforms market-leading competitor in detection of cervical pre-cancer.

Melbourne, 4th September, 2009

- Genera Biosystems (ASX: GBI) completes clinical study in conjunction with the Royal Women's Hospital, Melbourne on cervical smear specimens of more than 800 women.

- PapType, Genera Biosystems' cervical cancer detection test, performed significantly better than Qiagen's Hybrid Capture 2™ test, a market leader in the US$350m HPV testing market, in the detection of cervical precancer in women with abnormal Pap smears.

- Testing with PapType resulted in significantly fewer false negative results (8.9%) than testing with Hybrid Capture 2 (20.9%). A false negative result is where the test fails to identify women with high grade cervical disease, which can advance to cervical cancer.

- Genera expects to receive a licence to manufacture diagnostic tests from the Australian Therapeutic Goods Administration in the next few weeks.

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Genera Biosystems today released the results of a major clinical study on its PapType Human Papillomavirus (HPV) detection assay, carried out in conjunction with the Royal Women's Hospital (RWH), Melbourne, Australia. The RWH is a World Health Organisation Reference Centre for the study of HPV.

The study was carried out on specimens collected from 894 women who were referred to the hospital for further examination, after receiving abnormal Pap smear results. In addition to being tested with PapType, the specimens were also tested using Hybrid Capture 2™, manufactured by Qiagen of the Netherlands, which is currently the clear market leader in the US$350 million HPV testing market. The objective of the study was to compare how well the two tests performed in the detection of histologically proven high grade cervical pre-cancerous lesions – that is, high-grade precancerous changes, identified and confirmed by a pathologist examination of tissue specimens.

Critically, significantly fewer false negative results were returned by PapType than by HC2. HC2 returned 111 false negatives out of the 531 specimens shown by histology to be positive for cervical pre-cancer (a rate of 20.9%), compared to just 47 from PapType (8.9%). A false negative result is where a diagnostic test fails to correctly identify a patient with disease; in practice, this would mean that significantly more women would have undetected cervical pre-cancerous lesions if tested with HC2, than with PapType.

“This is an excellent result for PapType, and confirms the superiority over HC2 that was hinted at by our pilot study, the results of which were released late last year” commented Dr. Allen Bollands, Chief Executive of Genera. “In PapType, we have a test which is not only competitive in terms of its operational features, but also in the value of results that it generates. HPV testing is forecast to become a billion dollar-plus market, and with appropriate commercial backing, there’s no reason why PapType couldn’t account for a significant portion of that.”

The study also showed that, as the cervical pre-cancer advances towards full-blown cancer, PapType’s likelihood of detecting it also increases. Three hundred and twenty-seven of the women in the study were histologically shown to have CIN3 (the most serious form of cervical pre-cancer), or actual cancer. PapType had a false negative rate amongst these women of just 5.5%, compared to 16.2% for HC2.

Interestingly, three of the HC2 false negatives were called as “Indeterminate” by PapType. A PapType “Indeterminate” result occurs when the test is unable to detect any human DNA in the specimen, indicating the possibility of specimen mishandling. In a clinical situation, with PapType, this would lead to a retest. The HC2 test does not have such a “human control”, meaning there is no way of distinguishing a genuine HPV negative result, from one caused by an absence of specimen. PapType’s “human control” means that there will be a reduced chance of false negatives occurring for this reason.

Unlike HC2, PapType not only is able to detect the cancer-causing types of HPV, but can simultaneously and specifically identify the different genotypes causing the infection. The study also reported a high level of correlation between the genotypes detected by PapType and those detected by a reference HPV genotyping test, manufactured by Roche. Importantly, clinical trial scientists at RWH considered that the automation of genotyping results generation for PapType was more reliable than the manual process involved in the Roche assay. “Having numerical “bead count” cut-off values for each genotype (as per PapType assay) allows for better consistency/reproducibility in reading the data, as opposed to the visual signal intensities offered by Linear Array genotyping” said Dr. Matthew Stevens of RWH, who carried out the study.

“These results are very encouraging, and show that PapType can certainly be a very effective tool in the management of women with cervical disease” said Professor Suzanne Garland, of the Royal Women’s Hospital and a world-leading authority on HPV infections. “The medical literature on HPV clearly shows that there is a role for HPV genotyping assays, in order to identify those women chronically infected with specific high risk HPV types. That PapType can simultaneously detect as well as genotype, particularly for HPV 16 and 18, the commonest causes of cervical cancer, puts it in a class alone. The only two currently FDA-approved assays do not give simultaneous genotype detection”. Professor Garland is also a member of Genera’s scientific advisory board.

“We’re coming to the endgame for the commercialisation of PapType, and these splendid results are the first of three key announcements that we expect to make over the coming few weeks and months, that will eventually result in PapType being brought to market around the world” said Genera chairman, Fernando Careri. “In the next few weeks, we expect confirmation from the Australian Therapeutic Goods Administration that we will be receiving our manufacturing licence, meaning that we can be confident that we’re manufacturing PapType to the standards required in all major regulatory jurisdictions. Finally, we’re also in detailed discussions with a number of industry partners in regards to the commercial rollout of PapType. Whilst it’s extremely difficult to predict how long these negotiations will take, and what the eventual outcome will be, I’ve been extremely encouraged by the tenor of discussions to date.”

Further details:

Dr Allen Bollands
CEO Genera Biosystems Limited
Telephone: +61 (0)423 943 600
e-mail: allen.bollands@generabiosystems.com

About Genera Biosystems:

Genera Biosystems Limited (ASX: GBI) is a molecular diagnostics company that develops, manufactures and distributes advanced molecular diagnostic tests. Its first product, PapType™, a test which simultaneously detects and genotypes human papillomavirus, is on sale in Australia through Healthscope. International registrations are expected in 2009. The company has a development pipeline of products including novel tests for *Chlamydia trachomatis*, and *Neisseria gonorrhoeae*.

About cervical cancer:

Cervical cancer is the second most common cancer for women worldwide, after breast cancer. Each year there are about 466 000 new cases globally, and around 232 000 women die of cervical cancer. In 2004, there were 718 new cases in Australia. Virtually all cases of cervical cancer are caused by

high-risk HPV. Genital HPVs are the commonest sexually transmitted viral infection. For more information on HPV and cervical cancer, visit http://www.cervicalscreen.health.gov.au.