



ASX Release

Genera Biosystems receives TGA approval for its PapType HPV detection and genotyping test

Melbourne, 22nd January, 2010

- **PapType, Genera Biosystems' HPV test receives approval from the TGA**
- **Genera Biosystems has appointed Lazard as its financial adviser to advise on transaction options available for PapType commercialisation**
- **Repeatability/Reproducibility study successfully completed**

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Genera Biosystems today announced that the Australian Therapeutic Goods Administration (TGA) has approved the entry of the company's PapType Human Papillomavirus (HPV) test kit onto the Australian Register of Therapeutic Goods (ARTG). The company is now permitted to supply PapType to Australian customers, subject to the terms of the licence.

"This is a very significant, and tremendously satisfying achievement for everyone associated with our company" commented chairman, Mr. Fernando Careri. "To have taken a technological concept, and turned it into a product which will contribute to the health and well being of Australian women is something of which we should be extremely proud. Genera is already engaged in broad commercial discussions, and will now also engage in discussions with women's health specialists around the country to investigate how PapType might be incorporated into national cervical cancer screening guidelines".

Professor Suzanne Garland, of the Royal Women's Hospital, Melbourne, and chairman of the company's scientific advisory board welcomed the announcement, and noted that it was very timely, given new data that demonstrates the value of HPV testing in cervical cancer screening. "Particularly in women over 35 years of age, it's now very clear that HPV testing detects high-grade pre-cancerous lesions more effectively than Pap smears", said Professor Garland. "In addition, it's also likely that cervical screening methods based around HPV testing will allow longer periods between tests", she added.

PapType is already on sale through a pre-existing agreement with Healthscope (ASX: HSP). More widespread availability will follow from a successful conclusion to partnering discussions. "The notification from the TGA, whilst being extremely good news, has come somewhat earlier than we were anticipating", said General Chief Executive Officer, Allen Bolland. "We are focused on finalising a commercial relationship that maximises the value of the PapType to our company, and naturally, we want to ensure that any commercial activities, both in Australia and elsewhere, are aligned with our eventual partner's needs".

Genera has appointed Lazard, one of the world's preeminent financial advisory and asset management firms, to advise the company on its transaction alternatives. "Appointing Lazard to support the board in these critical matters has given our company access to a first-rate, global organisation with an outstanding track record in delivering creative solutions to maximise shareholder value", said Fernando Careri. At the recent Genera AGM, the company advised its shareholders that the company hoped to announce a partnership agreement during the first quarter of calendar 2010. Whilst Genera and Lazard continue to work to this timetable, progress will necessarily be determined to an extent by partners' timelines.

The company also announced the successful completion of the PapType repeatability and reproducibility study with its strategic partner Sonic Healthcare (ASX: SHL). The study, designed to demonstrate that PapType

performed equivalently between different operators, different laboratories and at different times, demonstrated that the product comfortably exceeded its targeted study endpoints of 95% repeatability and reproducibility.

Further details:

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About Genera Biosystems:

Genera Biosystems Limited (ASX: GBI) is a molecular diagnostics company that develops, manufactures and distributes advanced molecular diagnostic tests. International registrations are expected in 2010. 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.