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GENERA BIOSYSTEMS LIMITED (ASX: GBI)
RECEIPT OF DATA FOR PAPTYPE® >2,000 SPECIMENS IN US BASED SCREENING POPULATION

Genera Biosystems Limited ('Genera') is pleased to advise that it has received the results from over 2,000 cervical screening specimens collected in a United States-based screening population. The evaluation was undertaken by the University of New Mexico, Health Sciences Center – School of Medicine, Department of Pathology, ('UNMHSC').

Genera has received under confidentiality data from UNMHSC as well as an analysis on the data set performed by Prof. Jack Cuzick's group at the Wolfson Institute of Preventive Medicine (London, UK).

The Company is pleased to report that the data are broadly consistent with prior data generated by PapType® in other numerous clinical studies in both referral and screening populations in the detection of CIN2+[1].

Richard Hannebery, Genera Chief Executive Officer commented, "We are very pleased with the results showing sensitive detection of CIN2+ and CIN3+ as it represents the strong performance of PapType® in an independent clinical study."

"We have been looking forward to receiving this US screening population study data and it is a privilege to work with a global center of excellence in cervical cancer screening research such as the UNMHSC led by Dr. Cosette Wheeler as Principal Investigator."

Since 2006, Dr. Wheeler has directed a state-wide surveillance program in New Mexico that represents a one-of-a-kind US resource which captures all Pap and HPV tests, and all cervical, vulvar, and vaginal pathology under state regulations for all New Mexico residents. The goal of this monitoring program, which interfaces with a state-wide immunization registry as well as health plan

[1] Should squamous cervix cells be abnormal they are called cervical intraepithelial neoplasia (CIN). They are graded according to how deep the abnormal cells are within the surface of the cervix. This is detected by taking a sample of tissue biopsy from the surface of the cervix. Early changes are graded as CIN 1, and they will usually disappear without treatment. Further abnormal changes are graded as CIN 2 or CIN 3 and will require treatment. Treatment for CIN 2/3 may include cryotherapy, laser therapy, loop electrosurgical procedure (LEEP), or cone biopsy to remove or destroy the abnormal tissue.

billing data for vaccine delivery, is to assess real world HPV vaccine impact and effectiveness as a requisite to appropriate integration of screening and vaccination in the United States.

Genera has now been involved in a number of independent clinical studies in Australia, the UK and now the US involving in excess of 11,000 patient samples in both referral and screening populations overseen by world opinion leaders in cervical cancer screening. The performance of PapType® has been largely consistent across all studies providing confidence in PapType's robust clinical performance, reliability and reproducibility.

Genera believes this additional milestone further validates the significant resources it has applied to the development of PapType® and its protection via a robust portfolio of patents that have been granted in all key global jurisdictions including the US market which runs to 2025.

Richard Hannebery added, "This was the first independent clinical study we have undertaken with PapType® running on the Beckman Coulter CytoFLEX™ instrument. While we were extremely confident going into this study, having over the past 18 months undertaken extensive testing and validation of our AmpaSand assays running on the Beckman CytoFLEX™, it is always pleasing to deliver on the data."

Full public disclosure of the data will be made by Drs. Wheeler and Cuzick through peer reviewed publication.

Dr. Mario Koksch, Vice President and General Manager of Beckman Coulter's Cytometry Business Unit said, "We congratulate Genera on the great data set delivered by PapType® running on the CytoFLEX™ and we look forward to continuing to collaborate and partner with the Genera team to build on the strong relationship we have formed over the past few years. Beckman Coulter has a strong pedigree in providing robust world class instrumentation systems incorporating user friendly workflow for both researchers and clinical laboratories and we look forward to exploring what else we can do together to further improve the customer experience in running Genera's AmpaSand® based tests."

Paptype's commercial prospects and global market position

PapType® is one of only a few commercially available CE marked HPV tests that simultaneously detects and genotypes all 14 carcinogenic strains of HPV. The 14 carcinogenic HPV types have different abilities to infect, persist and cause cervical disease and it is persistent infection with the **same** carcinogenic HPV type that is the cause of 99.7% of all cervical cancer.

There is currently no comprehensive genotyping HPV test approved by the US FDA, with only 3 HPV tests approved for cervical cancer screening and of these FDA approved tests only the Roche Cobas® HPV test offers limited simultaneous genotyping of HPV types 16 & 18. Richard Hannebery commented, "The rising body of clinical data we have generated with PapType®, alongside the advances in instrumentation capability that we see before us, gives us a high degree of confidence that with the right partners a successful US FDA regulatory submission could be delivered by late 2018, which if successful, could change the game in comprehensive cervical cancer screening for women."

Genera is currently undertaking an additional significant clinical study in ~6,650 patient samples at the Wolfson Institute (UK) also using the Beckman Coulter CytoFLEX™ instrument. This study is well underway and Genera currently anticipates receiving this key additional clinical data during the month of November.

Outside of these clinical studies, in late June Genera submitted a commercial supply tender for a significant state government funded project to screen half a million women in a rural and semi-urban district of Thane near Mumbai, over a period of 5 years. The project aims to screen 100,000 women annually and will use a combination of Visual Inspection as a primary screen followed by reflex to HPV DNA testing (PapType®) and thereafter reflex again to HPV RNA testing.

This program is the largest state government sponsored cervical screening program incorporating both HPV DNA and RNA testing ever undertaken within India.

A full HPV genotyping assay that is validated in a screening population may deliver comfort for women not being at risk of cervical cancer as well as provide additional useful clinical information identifying persistent infection of certain higher risk carcinogenic HPV types.

Richard Hannebery added, "Persistent infection with carcinogenic HPV types 16 and 18 account for ~70% of all cervical cancers. The remaining ~30% incidence, not an inconsequential percentage of cervical cancer, is largely the result of persistent infection with an individual carcinogenic HPV type[2] of the 12 carcinogenic HPV types other than 16 and 18. Of these, HPV types 31, 33, 35, 45 and 52 are the most dangerous with HPV type 33 potentially being as deadly as HPV type 16 if contracted by a woman and infection persists."

"PapType's ability to simultaneously and individually detect all carcinogenic HPV types may offer women increased peace of mind while also providing better information to clinicians to facilitate more informed treatment decisions and surveillance."

HPV testing in Australia

On May 1st 2017, Australia is adopting a new cervical screening regime that will involve HPV testing replacing the traditional Pap smear as the front line screening diagnostic test. As result of the newly adopted screening algorithm the volume of HPV tests will rise from the current level of ~55,000 tests per annum to in excess of 1,300,000 tests per annum **(See Appendix 1)**. This higher volume of tests to be undertaken does not include 'reflex' HPV genotyping tests that may be offered by physicians in order to glean full HPV genotyping information for patients.

Genera currently intends to apply to MSAC for inclusion of its PapType HPV test on the Medicare Benefits Schedule as a screening test. The additional information offered by PapType® and flexibility of Genera's Q-Plots™ reporting software will allow Genera's PapType® test to be also offered as a reflex test, as well as a screening test, and in doing so providing additional revenue streams to pathology customers alongside more informed treatment decisions and surveillance for clinicians and their patients.

[2] Persistent multiple HPV type infections may also cause cervical cancer. For example a woman at high risk of developing cervical cancer may have persistent infection of both HPV type 33 and type 52.

The global market opportunity for HPV testing is expected to exceed ~US$1.5 to US$2 billion per annum as numerous countries follow Australia's lead in replacing the traditional Pap smear with HPV testing as the front line screening tool in the fight against cervical cancer in women. The Netherlands and Italy have also implemented national screening programs similar to what Australia is formally adopting on May 1st 2017 with Germany expected to follow. A high performing HPV test partnered with a leading global IVD company could be expected to capture a significant portion of this market opportunity.

As a true, high throughput, plate based multiplex technology[3], outside of PapType®, the AmpaSand® platform has the flexibility and capability to offer pathology customers a broad menu of high value molecular diagnostic assays used by physicians to diagnose disease, make treatment decisions and monitor patients.

In addition to its CE marked PapType® HPV and RTIplex™ respiratory tests Genera, is currently focused on broadening its testing menu with the development of a number of new assays in the areas of sexually transmitted infections (STI's), HIV, Aneuploidy Screening for IVF and Circulating Tumor DNA.

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About Genera Biosystems: Genera Biosystems Limited ("GBI") is an Australian Securities 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™, both of which are CE marked with four additional products in the company's development pipeline. The company aims to roll out a menu of 10-12 high value molecular diagnostic tests over the next 12 to 18 months. Genera manufactures these products in its Therapeutics Goods Administration (TGA) certified manufacturing facility in Scoresby, Victoria, Australia.

[3] All 'plate based' Real Time PCR platforms can 'multiplex' utilising additional wells of a plate to test for additional target analytes. As such commercially, their multiplexing capability is restricted due to a direct trade-off with volume throughput per plate (96 or 384 well). Genera's AmpaSand® technology facilitates the multiplexing of up to ~150 target analytes **in a single well** of a plate.

About Cosette Wheeler Ph.D: Cosette Wheeler is the Program Director and Principal Investigator of NM-HOPES-PROSPR, is a UNM Regents Professor in the Departments of Pathology and Obstetrics and Gynecology at the University of New Mexico (UNM) Health Sciences Center. Her New Mexico research group has contributed for over 20 years to understanding the molecular epidemiology of human papillomaviruses (HPV) in cervical precancer and cancer. She has overseen a number of large-scale multidisciplinary population-based projects that have ultimately enabled advances in primary and secondary cervical cancer screening. She has authored over 150 peer-reviewed articles a number in top tier journals.

Research Interests: Dr. Wheeler's interests and productivity have spanned many facets of HPV-related cervical disease from development of nucleic acid-based HPV diagnostics, HPV phylogeny and global molecular variation, host and viral genetic risk factors of cervical disease outcomes, and she has led groups supporting clinical trials to assess the utility of both HPV testing (US National Cancer Institute ALTS trial) and HPV vaccines (Merck Gardasil phase I, II and III and GSK Cervarix phase II and III). Within the Gardasil and Cervarix phase III pivotal efficacy trials, her clinical trials group acted as a lead enrollment site for the US and North America. Dr. Wheeler is currently the director of one of five US National Cooperative Research Centers in Sexually Transmitted Infections (STI-CRC), the UNM Interdisciplinary HPV Prevention Center funded by the National Institutes of Allergy and Infectious Diseases and she directs a UNM dedicated clinical trial facility, the House of Prevention Epidemiology (HOPE). In 2006 she was presented the American Society of Coloposcopy and Cervical Pathology (ASCCP) Distinguished Scientific Achievement Award.

Dr. Wheeler's laboratory has acted as a reference laboratory for the World Health Organization (WHO) and has developed international HPV DNA standards reagents for the WHO. These standards were considered necessary for monitoring global implementation of HPV vaccines. She has served as a Research Associate for the US National Research Council and as a scientific fellow for both the US National Science Foundation and the American Social Health Association and she has acted as an advisor to the US Centers for Disease Control and the American Cancer Society as well the International Agency for Research on Cancer's (IARC), Cancer UK, and the Instituto Nacional de Salud Publica, Cuernevaca, Mexico in support of their efforts to understand and prevent cervical cancer in developing countries.

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APPENDIX 1 – Figure 6

Figure 6: Proposed Screening Pathway.[4]