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**ASX Announcement – GENERA BIOSYSTEMS LIMITED (ASX: GBI)  
RECEIPT OF PREDICTORS 3 CLINICAL DATA**

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Genera Biosystems Limited (**‘Genera’**) is pleased to advise that it has received summary clinical data from the 6,000 patient Predictors 3 study in a cervical cancer screening population from the Wolfson Institute of Preventive Medicine (London). The company wishes to advise that whilst the data delivered to it is in summary form only, it is consistent with prior data generated by PapType® in the Predictors 2 study, a 1,099 patient study in an ASCUS population also undertaken by the Wolfson Institute.

The performance of PapType® in the Predictors 2 study was comparable to other high sensitivity tests for detecting CIN2+ - approximately 95% sensitivity - whilst being capable of delivering additional information and substantially higher specificity when applying a diagnostic classification of oncogenic HPV genotypes by sequentially maximising Positive Predictive Values (PPVs).

Genera now intends to share the Predictors 3 data under confidentiality with its prospective global IVD partners. As the study was independently undertaken by the Wolfson Institute of Preventive Medicine and supported by Cancer Research UK Programme grants, full public disclosure of the data will be made upon Prof Cuzick’s group publishing its paper in a respected peer reviewed medical journal later in the year.

Genera is delighted to have been involved in the Predictors 3 study and appreciates the interest of the Wolfson Institute in including PapType® in this study which is the only head-to-head comparison of major commercially available HPV tests in a screening population in which all women were evaluated by all tests.

Richard Hannebery, Genera Chief Executive Officer commented, “We have been looking forward to completing this pivotal screening study for quite some time. While we acknowledge that significant delays preceded commencement of the study, as Genera progressed IVD partnering discussions that were pivotal to making a decision regarding the most appropriate instrumentation system with which to proceed, it is very pleasing to now be in receipt of this key data. We believe this milestone validates the significant resources we have 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.”

PapType® is the only commercially available IVD approved HPV test in the Predictors 3 study that simultaneously detects and genotypes all 14 oncogenic strains of HPV. The 14 high-risk HPV types

have different abilities to infect, persist and cause cervical disease and it is persistent infection with the same oncogenic HPV type that is the cause of 99.7% of all cervical cancer. A full HPV genotyping assay that is validated in a screening population may deliver comfort for women not being at risk of cervical cancer while avoiding unnecessary referrals to colposcopy.

The global market opportunity for HPV testing is expected to exceed 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 will soon implement a national screening program similar to Australia's with Germany expected to make the decision later in 2015. A high performing HPV test partnered with a leading global IVD company could be expected to capture a significant portion of this market opportunity.

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**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™, both of which are CE-IVD approved 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.

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**About the Wolfson Institute:** The Wolfson Institute was established in 1991 it has a staff of around 180 and is a centre of excellence in the epidemiology and preventive medicine. The institute's focus is the translation of research into public health strategies and their practical implementation - all dedicated to the reduction of disease and disability.

The Wolfson Institute's Centre for Cancer Prevention conducts research into the prevention of cancer with particular focus on preventive therapy and screening. The institute are involved in clinical trials and epidemiology and as such its work is essentially collaborative.

Activities encompass prevention studies, screening studies, treatment comparisons, prognostic factors and biomarkers for survival, and aetiological studies of risk factors and biomarkers for developing cancer. The analysis of data from these projects often requires the development of new mathematical and statistical techniques, and it has an active interest in the development of new methodology.

<http://www.wolfson.qmul.ac.uk/centres/ccp>