Genetic Signatures Announces Regulatory Approval for Complete Enteric Product Suite in Australia and Europe and Secures 3base™ Patent in USA

- **Australian and European regulatory approval allows enteric product unrestricted access to an enteric MDx market worth $86m**
- **US patent allowed for 3base™ conversion and workflow, expiring 2031**
- **Developments support Genetic Signatures' global expansion strategy**

Sydney, Australia, 20 June 2017: Molecular diagnostics company Genetic Signatures Ltd (ASX: GSS) has today announced that it has received Australian and European regulatory approval for its Enteric Viral Detection solution. This will allow the sale of the company's complete enteric suite within those regions, which represent 22% of the global molecular diagnostics market. Genetic Signatures has also received approval notification for one of the company's core **3base™** technology patents from the United States Patent and Trademark Office (USPTO), thereby improving protection for Genetic Signatures' unique intellectual property in the significant US market.

Traditional diagnosis of infectious gastrointestinal disease can be both incomprehensive and time consuming, two factors effectively addressed by the **3base™** *EasyScreen*™ real-time PCR assays, screening for all major gastroenteritis pathogens. With regulatory approval for the company's Enteric Protozoan, Enteric Bacterial and *C. difficile* detection products already in place, Genetic Signatures aimed to secure similar approval for its Enteric Viral Detection solution.

Following a rigorous performance approval process focused on sensitivity, specificity, reproducibility and stability, the Enteric Viral Detection has now received full regulatory approval in Australia from The Therapeutic Goods Administration (TGA). Similarly in Europe the entire *EasyScreen*™ Enteric Pathogen Detection Kit range can now carry the CE-IVD marking, allowing its sale in that region.

"With this important regulatory milestone comes the realisation of a significant offshore opportunity and the possibility of unrestricted sales in 31 countries with a market estimated at $86m per year," said John Melki PhD, CEO of Genetic Signatures. "We will now continue to work on securing similar approvals for our STI and respiratory products."

In a further positive development Genetic Signatures has also been notified by the USPTO, the US agency responsible for granting patents for the protection of inventions, that one of the company's core **3base**™ patents ("Molecular Detection Assay using Direct Treatment with a Bisulphite Reagent") has been approved. Genetic Signatures' unique transformational MDx technology simplifies the detection of microbial targets and enables customers to identify a wider array of patient infections, delivering more accurate results in hours rather than days by conventional methods. The **3base**™ technology is found in the company's enteric, respiratory and STI product suite currently used by customers around the world.

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Importantly, in the United States, Genetic Signatures is currently preparing its products for full FDA approval and unrestricted sales. In a competitive market worth an estimated $1.26b and representing 50% to 60% of the global molecular diagnostics market, the securing of intellectual property is paramount and this new patent covers the 3base™ conversion process as well as the current associated workflow that has proven to be popular in customer labs until 2031. A similar patent has already been issued in Australia, Europe, Japan, New Zealand, Singapore and South Africa and is pending in other jurisdictions.

"Collectively these approvals and associated developments will help drive the company's global expansion strategy as we develop our footprint and grow new revenues from within the United States, Europe and at home in Australia whilst also playing a pivotal role in improving global health" said Dr. Melki.

For further information, see our website (www.geneticsignatures.com) or contact us as below:

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About Genetic Signatures Limited: Genetic Signatures is a specialist molecular diagnostics (MDx) company focused on the development and commercialisation of its proprietary platform technology, *3base*™. Genetic Signatures designs and manufactures a suite of real-time Polymerase Chain Reaction (PCR) based products for the routine detection of infectious diseases under the *EasyScreen*™ brand. Genetic Signatures' proprietary MDx *3base*™ platform technology provides high-volume hospital and pathology laboratories the ability to screen for a wide array of infectious pathogens, with a high degree of specificity, in a rapid throughput (time-to-result) environment. Genetic Signatures' current target markets are major hospital and pathology laboratories undertaking infectious disease screening.