ASX Announcement 4 June 2024

FDA Clearance For Gastrointestinal Parasite Detection Kit

Genetic Signatures Limited [ASX:GSS] ("GSS" or the "Company"), a global molecular diagnostics company announces that the US Food & Drug Administration ("FDA") has cleared the Company's *EasyScreen*™ Gastrointestinal Parasite Detection Kit and GS1 automated workflow[1] for marketing and sale in the US.

Genetic Signatures' *EasyScreen*™ Gastrointestinal Parasite Detection Kit has the broadest coverage of the FDA cleared molecular tests and is able to identify 8 of the most common and clinically relevant gastrointestinal parasites in a single test, representing approximately 90%[2] of all gastrointestinal Parasitic infections in the US. Genetic Signatures' *EasyScreen*™ Gastrointestinal Parasite Detection Kit is highly automated and is able to provide a result for all 8 targets in approximately 5 hours.

The current practice for gastrointestinal parasite testing is predominantly microscopic examination using O&P[3] testing, that is time-consuming, labour intensive, slow to provide a result, of variable sensitivity and frequently has poor patient compliance across multi sample protocols. It is estimated there are approximately 65 million annual cases of parasitic gastrointestinal infections in the US which result in approximately 5.5 million O&P tests each year.

Genetic Signatures is well-prepared for the commercial launch of its *EasyScreen*™ Gastrointestinal Parasite Detection Kit. The Company has installed instruments and completed training at nine customer-experience sites which span a range of customer groups including hospitals, health departments and corporate pathology providers under a customer-experience program. The Company has received positive feedback from these sites and expects some will become the initial commercial customers. Furthermore, the CPT codes which are relevant for providing reimbursement to end users from both public and private payors have been identified. Genetic Signatures expects first commercial sale of the kit in the US within 60 – 90 days of this clearance once appropriately packaged and labelled product is available and the Company's pathology provider customers have completed their internal technology evaluation and approval process.

"We are very excited to have secured our first FDA clearance for a unique and highly differentiated molecular test based on our proprietary **3base®** *technology"* said **Neil Gunn, Interim CEO**. *"This has been a key focus for the Company as the US is the largest single market for molecular diagnostics representing approximately 40% of the global market. We believe the unique configuration of our test combined with the significant operational efficiencies and potential impact on patient management will make this an attractive product for laboratories and pathology providers in the US."*

[1] A Genetic Signatures Automated System for Sample Preparation and PCR Set-Up

[2] Advances in Gastrointestinal Parasite Testing: Molecular Parasite Investigations – A Genetic Signatures Whitepaper 2024

[3] Ova & Parasite

Genetic Signatures will hold an online investor presentation to discuss the US FDA clearance of its EasyScreen™ Gastrointestinal Parasite Detection Kit at 11:00am (AEST) on Tuesday, 4 June 2024.

This presentation can be viewed live via Zoom. To register at no cost, please copy and paste the following link into your internet browser.

Investor Zoom Webinar 11:00am AEST Tuesday 4 June 2024

You are invited to register using this link

https://us06web.zoom.us/webinar/register/WN_WqZxnplySSueoIWiNXg3vA

Participants may submit questions during registration or during the session

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 hospitals and pathology laboratories undertaking infectious disease screening. Genetic Signatures is leveraging strong COVID-19 related sales of its *EasyScreen*™ respiratory kits and the growing interest in its gastroenteritis products to further commercialise its 3base® technology to rapidly and cost effectively screen for a wide array of infectious pathogens including antibiotic resistant bacteria, sexually transmitted infections, meningitis and mosquito borne viral diseases.