Genetic Signatures

ASX Announcement 4th September 2023

FDA 510(k) APPLICATION FOR GASTROINTESTINAL PARASITE DETECTION KIT SUBMITTED

- 510(k) application submitted to US FDA for *EasyScreen*™ Gastrointestinal Parasite Detection Kit
- Significant advantages over currently available diagnostic approaches and products
- Preparations for the anticipated commercial launch are well underway
- Initial commercial sales expected to commence shortly after receiving FDA clearance
- Clinical studies to support a second FDA 510(k) submission on track to complete in H1 CY2024

Genetic Signatures **[ASX:GSS],** a global molecular diagnostics company, is pleased to report that it has submitted a 510(k) application to the Food and Drug Administration (FDA) for regulatory clearance to market its *EasyScreen*™ Gastrointestinal Parasite Detection Kit in the United States (US).

The US represents a significant commercial opportunity for Genetic Signatures' *EasyScreen*™ Gastrointestinal Parasite Detection Kit, with an estimated Total Addressable Market (TAM) of 5.5 million tests per annum. Currently in the US, the diagnosis of gastrointestinal (GI) protozoan infections primarily relies on sample culture and microscopy, supported by antigen detection and pathogen-specific molecular tests. This approach is well recognised as being time-consuming, of variable reliability, labour-intensive and can take several days to provide a result. The extensive clinical trial data shows that Genetic Signatures' *EasyScreen*™ Gastrointestinal Parasite Detection Kit provides an effective, rapid molecular test that covers the eight most common and clinically relevant GI parasites.

Genetic Signatures' *EasyScreen*™ detection kits for GI infections are already available in Australia, Europe and Canada. Customer sites that have adopted this *EasyScreen*™ detection kit and workflow for syndromic GI screening have found it to provide a faster time to result, greater reliability and workflow efficiencies.

"Since using Genetic Signatures' molecular panel for GI infections, I am able to rationalise and streamline our workflow. That allows for significant staff savings and cost savings. We routinely screen all of our patients for protozoan parasites and we've picked up infections that would have been missed by not using molecular screening methods. I think there is a definite benefit to the patient. The only reason we would do microscopy now is if it's a specific request for something that is not on the molecular panel."— **Laboratory Manager at an existing customer site**

The 510(k) submission includes data from 1,500 clinical samples collected from three different sites across the US. The *EasyScreen*™ Gastrointestinal Parasite Detection Kit includes a number of GI pathogen targets that are currently unavailable in other existing commercial products. The absence of available predicate tests for specific pathogen targets also necessitated Genetic Signatures to develop new validation methodologies for the FDA 510(k) submission. While this delayed filing of the submission by a few months, it has also highlights the limited number of commercially available tests that will compete in the market for this diagnostic solution.

"Using this diagnostic parasitology panel will lead to more rapid and accurate identifications of the key parasite pathogens, resulting in clinically relevant results and better patient outcomes."— said **Lynne Garcia**, a recognised leader in diagnostic parasitology based at LSG & Associates in Los Angeles

Genetic Signatures has commenced preparations for the anticipated commercial launch of its *EasyScreen*™ Gastrointestinal Parasite Detection Kit once it is cleared by the FDA, including the additional recruitment of direct sales and support staff, and investment in local warehousing and laboratory facilities. The elevation of brand awareness in the US has also been supported by the delivery of a three-part educational webinar series, hosted by 360Dx. This webinar series describes key parasites causing GI disease, the challenges and limitations of traditional diagnostic methods for testing, and the benefits of employing a molecular approach. The Company also held a focus group with eight Key Opinion Leaders (KOLs) in the US to further understand laboratory needs and testing requirements for GI parasite testing, and the appeal of its patented **3base**® technology, which underpins the *EasyScreen*™ Gastrointestinal Parasite Detection Kit. Genetic Signatures' molecular solution and unique technology was positively received by these KOLs.

Now that the 510(k) application has been submitted with the FDA, Genetic Signatures has commenced work with a number of carefully selected, pre-qualified customer experience sites in the US to evaluate the *EasyScreen*™ Gastrointestinal Parasite Detection Kit. Genetic Signatures expects many of the customer experience sites will become initial customers for this syndromic solution.

"We are very excited to achieve this significant milestone and I am very appreciative of the hard work that has been done by the staff at Genetic Signatures, our advisors and the clinicians," said **John Melki, Managing Director and CEO of Genetic Signatures.** *"The US is the largest, single market for molecular diagnostic tests and represents significant opportunity for our EasyScreen™ Gastrointestinal Parasite Detection Kit. With a greater range of GI parasite targets provided in this syndromic solution, and the unique advantages of our **3base**® technology to detect these parasites, it is the ideal product to launch into the US market. Our plan to achieve additional product registrations in the US continues, with clinical studies to support a FDA 510(k) application of a second **3base**® product already underway. This is a molecular syndromic test for key viral respiratory infections in a single test."*

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.