ASX Announcement 26 July 2022

CLINICAL TRIAL RECRUITMENT COMPLETED FOR US ENTERIC KIT

Test specifically designed to address major US market need

Genetic Signatures **[ASX:GSS],** a global molecular diagnostics company, is pleased to announce it has completed recruitment for the clinical trial of their **3base**® *EasyScreen*™ Enteric Protozoan Diagnostic Kit in the United States (U.S). This is an essential step to support an application to the Food and Drug Administration (FDA), with submission of a 510(k) application planned during the 4th quarter of CY2022. Once cleared, Genetic Signatures will market this unique syndromic PCR test to the U.S. market.

Gastrointestinal parasites are a significant healthcare burden in the U.S., with more than 350 million cases of acute gastrointestinal infections reported annually. Globally, protozoan infections are among the leading contributors to the diarrhoeal disease load[1,2] and the leading cause of mortality of children under five years old[3,4]. Rapid and accurate identification of pathogenic parasites is critical to providing appropriate patient management.

Genetic Signatures' *EasyScreen*™ Enteric Protozoan Diagnostic Kit uses the Company's proprietary **3base®** technology to analyse the genetic profiles of protozoan pathogens. This allows, in a single sample, the rapid and accurate detection of up to eight species of clinically relevant gastrointestinal parasites. Results from *EasyScreen*™ tests are available within hours, compared with days or weeks for culture-based methods, and are typically able to identify more infections than traditional methods.

To support Genetic Signatures' 510(k) application, the FDA required the Company to provide data from 1,500 clinical samples collected across three different sites in the U.S. Due to the innovative test design and broad content the samples will be analysed for comparative purposes using commercially available tests where available or with in-house developed validated comparative tests, where no commercially available predicate exists. Once completed, Genetic Signatures anticipates an FDA 510(k) application for its *EasyScreen*™ Enteric Protozoan Diagnostic Kit to be submitted during the 4th quarter CY2022, after which the FDA will review the application. The FDA has a goal of responding with a decision 90 days from submission.

Tomorrow morning, Sydney time, there will be a Genetic Signatures sponsored webinar[5], the second of a three-part series, where two leading experts in medical diagnostics, Lynne Garcia and Damien Stark will be presenting evidence for the tremendous clinical advantage in testing both immunocompetent and immunocompromised patients with diarrhea using molecular testing.

"After facing considerable recruitment delays due to the COVID-19 pandemic, we are very pleased to have achieved this significant milestone," said Chief Executive, Dr John Melki. "Our enteric product range has attracted a great deal of commercial attention, reflecting the breadth of targets able to be identified in a single test. In the U.S. the primary diagnostic methods for identifying protozoa rely on culturing and visual identification (microscopy) which are time consuming and have variable sensitivity. By contrast, PCR tests have been shown to be quick and highly accurate.

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[1] Fletcher SM, Stark D, Harkness J, Ellis J. Enteric protozoa in the developed world: a public health perspective. Clin Microbiol Rev. 2012 Jul;25(3):420-49. doi: 10.1128/CMR.05038-11. PMID: 22763633; PMCID: PMC3416492.
[2] Di Genova BM, Tonelli RR. Infection Strategies of Intestinal Parasite Pathogens and Host Cell Responses. Front Microbiol. 2016 Mar 3;7:256. doi: 10.3389/fmicb.2016.00256. PMID: 26973630; PMCID: PMC4776161.
[3] Zhang H et al. (2015), Multiplex polymerase chain reaction tests for detection of pathogens associated with gastroenteritis. Clin Lab Med, 35(2): 461–486.
[4] Sattar SBA & Singh S. (2020), Bacterial gastroenteritis. StatPearls Publishing.
[5] https://event.on24.com/wcc/r/3824640/BB9DAF7954D825288C71B0B9C85C1DC8

"The U.S. is a significant opportunity for our Enteric Protozoan Kit with an estimated Total Addressable Market (TAM) of 5.5 million tests per annum. We are targeting to gain 40% of the market within 5 years while also providing the introduction for utilisation of our other **3base®** *EasyScreen*™ molecular diagnostic kits."

Approved by Genetic Signatures' Board of Directors

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. 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.