

Decision to Cease Development of US Respiratory Product

- Strategic decision to conclude development of the *EasyScreen*[™] Essentials Respiratory Detection Kit for the US market due to increased competition and changing market dynamics
- Focus effort and investment on the anticipated imminent launch of the *EasyScreen*[™] Gastrointestinal Parasite Detection Kit in the US

Genetic Signatures [ASX:GSS] (“GSS” or “the Company”), a global molecular diagnostics company announces that, based on an internal assessment of the commercial landscape, it is concluding the development of the *EasyScreen*[™] Essentials Respiratory Detection Kit for the US market. As a consequence, the Company has ceased US clinical development activities for this product and no longer intends to file a 510(k) application to the US Food & Drug Administration for it as previously guided.

Following the increase in molecular testing for respiratory pathogens that occurred during the COVID-19 pandemic, Genetic Signatures commenced development of the *EasyScreen*[™] Essentials Respiratory Detection Kit specifically designed for the US market. This product focused on the most common US respiratory infections, including SARS-CoV-2, and the use of Genetic Signatures’ **3base**[®] technology to improve the potential to detect new, emerging strains of those respiratory pathogens. However, since the commencement of this product development program, several high-throughput, fully automated respiratory syndromic molecular tests have been cleared by the FDA and become established in the US market. In parallel, the molecular testing for respiratory pathogens has declined significantly over the past 24–36 months.

Given this rapidly changing market dynamic, the Company does not believe its benefits over established and recently cleared incumbent automated products are sufficient for it to secure a commercially meaningful share of this increasingly crowded market. In view of this, the management and the Board has decided to focus its near-term effort and investment on the anticipated imminent launch of the *EasyScreen*[™] Gastrointestinal Parasite Detection Kit in the US.

“While it is disappointing to conclude the development of a key product at this late stage, we are very mindful that any investment we make in new products must continue to be aligned with a compelling commercial opportunity” said **Neil Gunn, Interim CEO**. *“Based on our assessment of the commercial opportunity and the feedback we have had from our potential US customers, we are not sufficiently confident that our US Respiratory product will be able to rapidly win market share from the incumbent products in this increasingly competitive market. As a consequence, we have made the hard decision to not to proceed with any further investment into the development of this current version of our 3base[™] respiratory product and to focus our resources on the imminent launch of our Enteric product and other opportunities where we believe our 3base[®] technology will provide a competitive advantage and deliver the commercial outcomes we expect. We remain committed to our respiratory products in our domestic market of Australia where we see increasing use as the winter season arrives.*

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.

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