ASX Announcement 30 March 2020

First shipments and regulatory submissions for COVID-19 diagnostic test

- **European CE-IVD registration submitted for new 3base *EasyScreen*™ SARS-CoV-2 Detection Kit**
- **An application for TGA registration in Australia has also been submitted**
- **Confirmation of CE mark will allow the kit to be sold in UK and all European Union countries**
- **Genetic Signatures' new SARS-CoV-2 Kit is already being supplied to customers in Europe and Australia under regulatory exemptions at prices consistent with Genetic Signatures other products**
- **Analytical studies performed to date will support the upcoming US FDA application**

Further to our previous announcements (including in our half-year report released on 26 February 2020) that Genetic Signatures Limited (ASX: GSS, "**Genetic Signatures**" or the "**Company**") has supplemented its existing assays to specifically identify the 2019 novel strain of coronavirus (SARS-CoV-2), the virus that causes COVID-19, the Company today announces that it has submitted a formal application for European CE-IVD registration for a new real time PCR (polymerase chain reaction) assay that does this. The Company has also submitted an application for inclusion on the ARTG (Australian Register of Therapeutic goods). Confirmation of CE-IVD will allow for the continued marketing and supply throughout Europe and UK, as regulatory exemptions are for a defined period. Licensed Australian laboratories are permitted to self-validate the tests to use the kits commercially. The Company sells both directly to end users and through distributors in Europe.

Since the beginning of the year when it became apparent the COVID-19 outbreak was a serious global problem, Genetic Signatures has directed resources to develop a SARS-CoV-2 specific test utilising its unique **3base™** technology.

Data has been generated to support the submissions as required by the European IVDD (*in vitro* diagnostic directive) and TGA Medical Devices Regulation (ARGMD) to allow the product to be marketed as an *in vitro* diagnostic (IVD) in Australia and Europe. The data submitted for European approval will also support the planned FDA EUA (Emergency Use Authorisation) regulatory application in the USA in the near term.

CE-IVD marking and inclusion on the ARTG creates a significant opportunity for Genetic Signatures as laboratories and governments seek fast and accurate tests.

The Company has introduced laboratories in Europe and Australia to both the new test and its **3base™** technology and has manufacturing in place at its Sydney-based existing manufacturing facilities to meet anticipated initial high-volume orders.

Genetic Signatures CEO, Dr. John Melki said *"We recently increased our capabilities in Europe and are ready to serve hospitals and test labs across the UK and European Union.*

Customers will be able to use the test to screen for the SARS-CoV-2 on its own or as part of our existing EasyScreen™ Respiratory Pathogen Detection Kit which identifies more than 14 common respiratory pathogens.

"Our hope is it will help clinicians move faster and better manage their urgent work, to detection infection and save lives."

The current *EasyScreen™* Respiratory Pathogen Detection Kit and new SARS-CoV-2 Detection Kit can be used on high throughput instruments currently supplied by Genetic Signatures allowing for rapid detection of up to 188 patient samples in approximately 4.5 hours with minimal hands-on time for laboratory technicians.

As a global supplier of Covid-19 test kits Genetic Signatures expects it will be classified as an essential service and, as such will not see its operations unduly impacted by increasingly strict lockdowns. There are significant constraints in worldwide supply chains (logistics and raw material supply) though that may impact on our ability to supply product to more remote locations.

The recent trading halt was at the behest of ASX who sought confirmation of claims in the announcement.

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

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Announcement authorised by Genetic Signatures' Board of Directors

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.