G Medical Innovations Holdings Ltd
ARBN 617 204 743

ASX Announcement 20 May 2020

VSMS ECG Patch receives US FDA 'Emergency Use Authorisation' for patients being treated for COVID-19

- **Patch now authorised in the USA for emergency use for patients undergoing treatment for COVID-19**
- **Patch entitled for reimbursement under US CPT code scheme – adds to GMV's growing revenue profile**
- **Large addressable market for G Medical - ~1.5m confirmed cases of COVID-19 recorded in the US[i] so far**
- **Fast route to market - manufacturing ramp-up of patch now underway at established facility in Israel**
- **Patch will remotely monitor the QT syndrome prolongation on a patient's electrocardiogram – all data will be compiled with extensive reports sent to healthcare professionals and GMV call centres for analysis**

Medical device and telehealth company **G Medical Innovations Holdings Ltd (ASX: GMV**) ("G Medical" or "Company") is pleased to report a significant development for the Company with receipt of Emergency Use Authorisation ("EUA") status from the US Food and Drug Administration ("FDA") for the Company's Vital Signs Monitoring System ("VSMS") ECG Patch ("Patch") for the remote monitoring of the QT interval of an ECG in patients who are undergoing treatment in a hospital setting for COVID-19 with drugs that can prolong QT intervals and may cause fatal arrhythmias.

Prolonged QT intervals outline a rhythm disorder in the heart (medically known as an arrhythmia) whereby an individual's heart muscle takes longer to recharge between beats. This can potentially lead to fainting, seizures or sudden death.

Under the EUA 'Issuance of Authorisation', the FDA concluded that "there is no adequate, approved, and available alternative to the emergency use of the VSMS Patch for remote monitoring of the QT interval of an ECG in patients who are undergoing treatment in a hospital setting for COVID-19 with drugs that can prolong QT intervals and may cause life-threatening arrhythmias. In addition, remote monitoring may reduce the [Health Care Professionals] HCP risk of exposure to SARS-CoV-2 during the COVID-19 pandemic."[ii]

The Company will continue its manufacturing of the Patch at its wholly owned R&D facilities in Israel and also via an FDA and ISO certified medical device contract manufacturer in Israel, ahead of future production at G Medical's Guangzhou China production facility.

The Authorisation will be effective until the declaration that circumstances exist justifying the authorisation is terminated under section 564(b)(2) of the relevant Act or the EUA is revoked under section 564(g) of the Act.

Management commentary

CEO Dr Yacov Geva said: *"This authorisation from the FDA is an outstanding development for G Medical and its value cannot be underestimated. It is heartening to see that our technology has been recognised as being able to help ease the burden of COVID-19 on the US healthcare system.*

"G Medical is confident that the Patch can fill the shortage of ECG monitors that hospitals across the USA are facing and also reduce healthcare workers' exposure to the disease.

"Our products are effective and especially relevant during the current COVID-19 pandemic and we believe that they will remain so well beyond COVID-19 as hospitals and other medical facilities and organisations continue to push towards telehealth and remote patient monitoring."

Background on VSMS Patch and its applicability to COVID-19 patients

The Patch is part of the modular VSMS and is an easy-to-use, clinical grade solution used for monitoring patients through the healthcare lifecycle. The Patch streamlines and simplifies healthcare and patient monitoring by delivering continuous, 14 day recording of **6 channel ECG**.

US healthcare professionals can now use the Patch in a hospital setting to monitor the QT syndrome prolongation of a patient's electrocardiogram. The patch will be used to monitor patients who are 18 years of age or older and receiving treatment for COVID-19 with drugs that can prolong QT syndrome and may cause life-threatening arrhythmias.

QT syndrome prolongations are usually measured on a 12-lead ECG at various time points during drug exposures. However, the use of a 12-lead ECG for patients being treated for COVID-19 is burdensome and presents additional risk to patients and healthcare professionals due to the need for in-person consultations.

The FDA has now concluded that the Patch may be effective for remotely monitoring QT syndrome prolongations in COVID-19 patients and may reduce the risk of a healthcare professional's exposure to the disease.

Patients will be monitored for up to 14 days wearing the patch. During the monitoring period, the Patch will record and transmit ECG data, which will be saved and wirelessly transmitted to G Medical Diagnostic call centres for analysis. A call centre certified cardiographic technician will then compile the clinical findings and send an extensive report to the prescribing physician at the hospital.

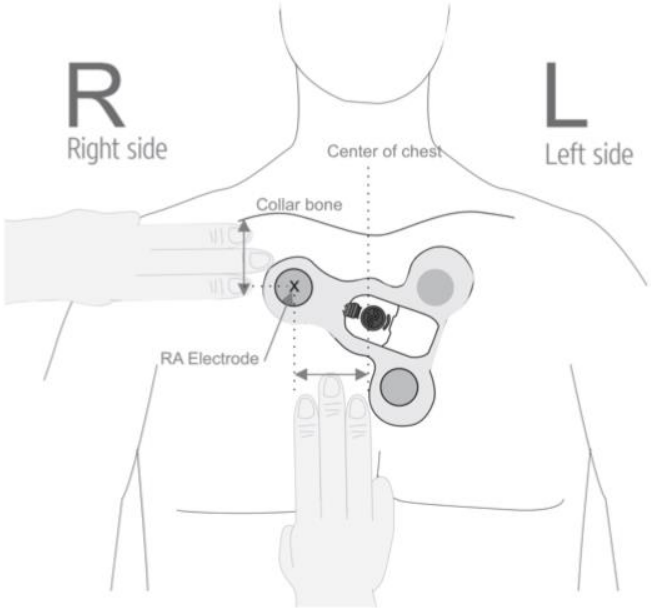

Image one: location of the Patch on the chest of the patient

Market opportunity and supply chain

There are currently over 1.46m confirmed cases of COVID-19 in the USA, with numbers expected to rise in the coming months. G Medical is confident that the Patch can help ease the burden healthcare professionals face due to COVID-19 and reduce workers' exposure to the disease.

G Medical has a robust and well-established supply chain including quality manufacturing facilities in Israel. The Company is now aggressively scaling production of the Patch at these facilities in anticipation of immediate demand that is likely to come from US hospitals and healthcare facilities imminently.

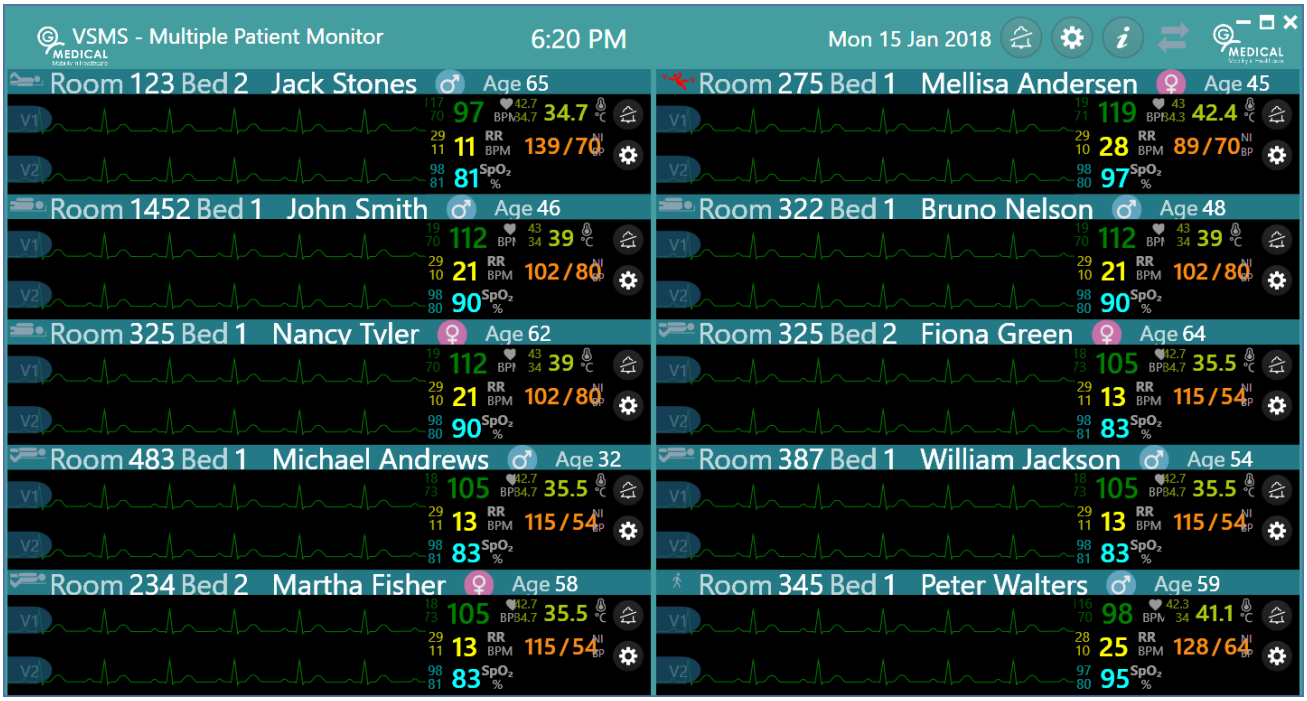

Image Two: VSMS – multiple patient monitoring - example

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Authorised for release by Yacov Geva, Managing Director.

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About G Medical Innovations

G Medical **(ASX: GMV)** was founded in August 2014, aiming to be at the forefront of the digital health revolution, developing the next generation of mobile health (mHealth) technologies. The Company leverages the experience and expertise of its Board to deliver best-in-class solutions to address this global opportunity.

The Company specialises in innovative next generation mobile and e-health solutions using its suite of proprietary devices and software solutions, as well as patient service operations, with a view to driving multiple and recurring revenue streams, across numerous verticals and territories.

For more information on G Medical, please visit www.gmedinnovations.com

About G Medical products:

G Medical offers a suite of consumer and professional clinical-grade products (with regulatory approval) that are positioned to streamline healthcare services, improve remote access to medical data, reduce costs, improve quality of care, and make healthcare more personalized and precise. Currently the Company is focusing on two main verticals.

The 'Prizma' Medical Smartphone Case is one of two key products developed by G Medical and is aimed at everyday consumers focused on their medical health and wellbeing. The 'Prizma' allows consumers to turn their smartphone into a mobile medical monitor to measure a wide range of vital signs, with the added advantage that users are able to store their medical data in the cloud and share it with third parties such as healthcare professionals and family members.

G Medical also offers a professional real-time patient continuous monitoring solution, G Medical's Vital Signs Monitoring System (VSMS) and G Medical Patch (GMP). This modular solution measures a wide range of vital signs that are automatically presented in a call centre (IDTF) or a hospital setting. The GMP assists in diagnosing patient complaints and conditions remotely, from pre-hospitalisation, hospitalisation and through to post discharge home-based settings.

[i] https://coronavirus.jhu.edu/map.html

[ii] https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations