



G Medical Innovations Holdings Ltd
ARBN 617 204 743

ASX Announcement

17 January 2020

PRIZMA CLINICAL TRIALS COMPLETED FOR CHINA NMPA APPROVAL PROCESS

- **Prizma device clinical trials with 208 patients completed across multiple hospitals in China**
- **Major milestone in the China regulatory approval process - potentially unlocks large market entry**
- **Trial results to be lodged with National Medical Products Administration in coming weeks**
- **NMPA approval will unlock G Medical's China market entry**

Mobile and e-Health company **G Medical Innovations Holdings Limited (ASX:GMV) ("G Medical" "the Company")**, is pleased to advise that it has successfully completed the necessary clinical trials required to obtain National Medical Products Administration (NMPA) (formerly China Food and Drug Administration or CFDA) approval for the use of its Prizma device in the People's Republic of China.

G Medical has completed the additional trials with 208 patients with three of its partner hospitals, the Guangzhou Women and Children's Medical Centre, the Zhujiang Hospital of Southern Medical University and the Sixth Affiliated Hospital of Sun Yat-sen University. As previously announced, the trials included measurements for electrocardiography (ECG), blood-oxygen saturation (SPO2) and body temperature using the Prizma device benchmarked against the relevant 'gold standard' hospital diagnostic equipment.

The Company is currently interpreting the large amount of statistical data generated and a dossier of results will be finalised for lodgement with the NMPA. G Medical expects to lodge the required information with the NMPA by the end of April 2020, and is confident that it will receive NMPA clearance for its Prizma medical device.

NMPA approval for the Prizma device will allow for the commencement of G Medical's commercial sales and services activities within the Chinese market. NMPA approval for the manufacture of the Company's medical devices has already been granted for its Guangzhou production facility, leaving it well positioned to capitalise once NMPA approval for the Prizma device is granted.

Further, on receipt, the NMPA approval for the Prizma device will allow G Medical to accelerate existing distribution and services arrangements with its China partners being; Beijing SilverLake Investment Co., Ltd ("SilverLake") and Shandong Boletong Information S&T Co. Ltd ("Boletong"), underpinning multiple potential revenue streams (in accordance with requirements to the respective agreements as previously announced).

The Company is continuing the NMPA regulatory approval process for its GMP 'Patch' (VSMS) and will provide further updates as developments are progressed.

CEO and Executive Director Dr Yacov Geva said: "The completion of these clinical trials is a major milestone for G Medical and an important step in securing our entry into the large Chinese market.

“The Company will shortly lodge the required documentation to the regulator and we are confident that NMPA approval will be received towards the middle of the year. Following this, the provisions for our device sales and services are expected to be able to materialise quickly via our existing established in-country partners, as well as to allow for additional partnerships to be explored.

“G Medical looks forward to updating shareholders as relevant information is lodged with the NMPA and further developments are made.”

Authorised for release by Dr Yacov Geva, CEO and Managing Director of the Company.

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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.