Shockwave Medical and Genesis MedTech Obtain Regulatory Approval in China for Intravascular Lithotripsy

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Approvals Cover Both Coronary and Peripheral IVL Catheters and Generators Manufactured by Shockwave

SANTA CLARA, Calif. and SINGAPORE, May 23, 2022 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development of Intravascular Lithotripsy (IVL) to treat severely calcified cardiovascular disease, and Genesis MedTech Group announced today that they have successfully obtained approval from China's National Medical Products Administration (NMPA) to market and sell the Shockwave IVL System with the Shockwave C^2 Coronary IVL Catheters and the Shockwave M^5 and S^4 Peripheral IVL Catheters in China. A joint venture between Genesis MedTech and Shockwave was formed in March of 2021 as a partnership to distribute Shockwave's products in China and to leverage Genesis MedTech's Wuxi research and development and production base to accelerate the manufacturing of Shockwave's products for the local Chinese market.

The Shockwave M^5 and S^4 IVL Catheters, which are used for the treatment of peripheral arterial calcification lesions, are approved in the United States, the European Union, and other select international jurisdictions and have been used to help treat more than 50,000 patients globally who suffer from peripheral arterial disease. The Shockwave C^2 Coronary IVL Catheters, which are used for the treatment of coronary arterial calcification lesions, are approved in the United States, the European Union, and other select international jurisdictions, and have been used to help treat more than 70,000 patients globally who suffer from coronary artery disease.

In July 2021, Professor Yundai Chen of the Chinese People's Liberation Army General Hospital led a team to perform the first clinical IVL procedure in China to treat a patient with severely calcified coronary artery lesions. "Shockwave IVL technology is an innovative solution for treating coronary artery calcification, especially when the calcium is deep in the artery. The technology is easy to use, which is good for increasing access," commented Professor Chen.

In August of 2021, Professor Weiguo Fu and Professor Zhihui Dong, both of Zhongshan Hospital (affiliated to Fudan University) led their team to successfully complete the first clinical IVL procedure in China on severely calcified lesions in peripheral arteries. Professor Fu said: "Shockwave IVL provides a powerful solution to calcified lesions that could not be effectively treated in the past. It is a promising and indispensable approach for the future."

With an aging population, there is an increasing incidence of calcified vascular disease in China. According to the *Chinese Expert Consensus on the Diagnosis and Treatment of Calcific Coronary Lesions 2021* (Expert Consensus Statement 2021), the risk of developing coronary artery calcification increases with age, with an incidence rate of about 50% in people aged 40-49 years and about 80% in people aged 60-69 years. Calcification is also a common problem in patients with peripheral arterial disease. According to *Statistica*, China had a population of over 1.4 billion in 2020, 50% of whom were over the age of 40.

"Approval in China represents another milestone in the international expansion for Shockwave's IVL technology. We are very appreciative of the work and the quick regulatory approval by the NMPA – despite the difficult conditions in China in the past months – and its recognition of IVL's clinical value for patients in China," said Doug Godshall, Chief Executive Officer of Shockwave Medical. "Genesis MedTech is a perfect partner for Shockwave in China and this accomplishment underscores the value of their established infrastructure and local relationships. We look forward to our continued relationship as we bring IVL to physicians and patients in China for treatment of arterial calcification.

About Genesis MedTech Group
Genesis MedTech Group is a medical device company headquartered in Singapore. Founded by a group of professionals and entrepreneurs with MedTech experience globally and in Asia, the company's product portfolio focuses on multi-therapy medical device products for emerging markets with sales and distribution through its established commercial network. Genesis MedTech Group covers the entire industry value chain of research and development, production, quality management, supply chain, marketing, and sales.
For more information, visit http://www.genesismedtech.com

About Shockwave Medical, Inc.
Shockwave is focused on developing and commercializing products intended to transform the way calcified cardiovascular disease is treated. Shockwave aims to establish a new standard of care for the interventional treatment of atherosclerotic cardiovascular disease through differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque, which the company refers to as Intravascular Lithotripsy (IVL). IVL is a minimally invasive, easy-to-use and safe way to significantly improve patient outcomes. To view an animation of the IVL procedure and for more information, visit www.shockwavemedical.com.

Forward-Looking Statements
This press release contains statements relating to our expectations, projections, beliefs, and prospects, which are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify these statements by forward-looking words such as "may," "might," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue," and similar expressions, and the negative of these terms. You are cautioned not to place undue reliance on these forward-looking statements. Forward-looking statements are only predictions based on our current expectations, estimates, and assumptions, valid only as of the date they are made, and subject to risks and uncertainties, some of which we are not currently aware.

Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others: the impact of the COVID-19 pandemic on our operations, financial results, and liquidity and capital resources, including the impact on our sales, expenses, supply chain, manufacturing, research and development activities, clinical trials, and employees; our ability to develop, manufacture, obtain and maintain regulatory approvals for, market and sell, our products; our expected future growth, including the size and growth

potential of the markets for our products; our ability to obtain coverage and reimbursement for procedures performed using our products; our ability to scale our organizational culture; the impact of the development, regulatory approval, efficacy and commercialization of competing products; the loss of key scientific or management personnel; our ability to develop and maintain our corporate infrastructure, including our internal controls; our financial performance and capital requirements; and our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others. These factors, as well as others, are discussed in our filings with the Securities and Exchange Commission (SEC), including in Part I, Item IA - Risk Factors in our most recent Annual Report on Form 10-K filed with the SEC, and in our other periodic and other reports filed with the SEC. Except to the extent required by law, we do not undertake to update any of these forward-looking statements after the date hereof to conform these statements to actual results or revised expectations

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