Shockwave Announces Decisions From the U.S. Patent and Trademark Office on Inter Partes Review Proceeding

July 8, 2020

SANTA CLARA, Calif., July 08, 2020 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development of Intravascular Lithotripsy (IVL) to treat complex calcified cardiovascular disease, announced today that the company received the initial rulings related to two of the *inter partes* review (IPR) cases that were initiated by Cardiovascular Systems, Inc. (CSI).

In December 2018, CSI filed petitions for IPR with the Patent Trial and Appeal Board (PTAB) of the U.S. Patent Office (USPTO) to challenge the validity of three of Shockwave's issued patents. CSI asked the PTAB to reconsider the original decision of the USPTO to issue those patents and asked that all claims of each patent be invalidated.

The PTAB ruled today that a key claim in U.S. Patent No 8,956,371 (the '371 patent) is valid. This claim is generally directed to a device that creates shockwaves inside of a balloon catheter that is delivered over a guidewire.

Further, the PTAB ruled today that some claims of the U.S. Patent No 8,956,371 are invalid and that all claims of U.S. Patent No 8,728,091 (the '091 patent) are invalid. Shockwave does not agree with the ruling that these claims are invalid. The IPR decisions are appealable to the U.S. Court of Appeals for the Federal Circuit, and Shockwave remains committed to prosecuting and protecting its patent portfolio to the fullest extent possible.

All claims of the '371 and the '091 patents remain valid and enforceable until appeals have been exhausted and Shockwave is not prohibited from selling or continuing to develop its IVL technologies.

"We are very pleased that the court validated claim 5 of our '371 patent, which protects the broad embodiment of our IVL technologies. Specifically, claim 5 describes a device that is delivered over a guidewire and generates shockwaves with electrodes inside of a balloon catheter. We believe that any viable, much less commercially viable, IVL device must contain these elements," stated Doug Godshall, President and Chief Executive Officer of Shockwave Medical. "While we disagree with the other invalidity findings of the PTAB, we believe we have strong arguments supporting the validity of all claims of both our '371 and our '091 patents and we intend to appeal this decision with the expectation that we will prevail in our appeal. We believe that our robust portfolio of 40 issued U.S. patents and 50 issued foreign patents captures and protects the truly unique and sophisticated IVL technology that has already helped over 30,000 patients with severely calcified arteries. Our business and pipeline remain compelling, our customer support is strong, and we remain highly committed to the continued advancement of IVL as a treatment for calcified cardiovascular disease."

Documents related to the IPR can be accessed on the USPTO's website at the following link: https://developer.uspto.gov/ptab-web/#/search/documents

About Shockwave Medical, Inc.

Shockwave Medical is focused on developing and commercializing products intended to transform the way calcified cardiovascular disease is treated. We aim to establish a new standard of care for the interventional treatment of atherosclerotic cardiovascular disease through our differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque, which we refer 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 Shockwave's expectations, projections, beliefs, and prospects (including statements regarding Shockwave's product development outlook), which are "forward-looking statements" within the meaning of the federal securities laws and by their nature are uncertain. Words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "plans," and similar expressions are intended to identify forward-looking statements. Such forward-looking statements are not guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements. Our business and operations are subject to a variety of risks and uncertainties and, consequently, actual results may differ materially from those projected by any forward-looking statements. Factors that could cause actual results to differ from those projected include, but are not limited to: the impact of the COVID-19 pandemic on our operations, financial results, and liquidity and capital resources, including on sales, expenses, supply chain, manufacturing, research and development activities, clinical trials and employees; our ability to design, develop, manufacture and market innovative products to treat patients with challenging medical conditions, particularly in peripheral artery disease, coronary artery disease and aortic stenosis; our expected future growth, including growth in international sales; the size and growth potential of the markets for our products, and our ability to serve those markets; the rate and degree of market acceptance of our products; coverage and reimbursement for procedures performed using our products; the performance of third parties in connection with the development of our products, including third-party suppliers; regulatory developments in the United States and foreign countries; our ability to obtain and maintain regulatory approval or clearance of our products on expected timelines; our plans to research, develop and commercialize our products and any other approved or cleared product; our ability to scale our organizational culture of cooperative product development and commercial execution; the development, regulatory approval, efficacy and commercialization of competing products; the loss of key scientific or management personnel; our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act; our ability to develop and maintain our corporate infrastructure, including our internal controls; our financial performance and capital requirements; and our expectations regarding 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 risks and uncertainties, as well as others, are discussed in greater detail 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. There may be additional risks of which we are not presently aware or that we currently believe are immaterial which could have an adverse impact on our business. Any forward-looking statements are based on our current expectations, estimates and assumptions regarding future events and are applicable only as of the dates of such statements. We make no commitment to revise or update any

forward-looking statements in order to reflect events or circumstances that may change.

Media Contact:
Scott Shadiow
+1.317.432.9210
sshadiow@shockwavemedical.com

Investor Contact:
Debbie Kaster
investors@shockwavemedical.com

Source: Shockwave Medical, Inc.