



CVR Medical Provides Update

DENVER, NC, USA, November 9, 2018 /EINPresswire.com/ -- CVR Medical Corp. (CVM.V) (TSXV: CVM) (OTCQB: CRRVF) ("CVR Medical") a Canadian listed and US based healthcare company in the medical device sector announces submission of the Carotid Stenotic Scan (CSS) to TUV Rheinland for electrical safety and EMC testing. TUV Rheinland is one of the leading providers of product safety certifications worldwide, covering an assortment of items such as medical devices, home appliances, audio/video products, medical products, textiles and telecommunication equipment. This testing is required for the CSS's subsequent De Novo submission to the FDA for US market clearance and will show that the device is compliant with all IEC 60601-1 requirements. IEC 60601 is a series of technical standards for the safety and essential performance of medical electrical equipment, published by the International Electrotechnical Commission. First published in 1977 and regularly updated and restructured, IEC 60601-1 is widely accepted as the benchmark for electronic medical equipment. Additional information about TUV Rheinland can be found here (<https://www.tuv.com/usa/en/>).

Tony Robinson, CVR Medical Chief Operating Officer commented, "It feels good to have the CSS in the hands of TUV and progressing through one of the critical final steps necessary for our FDA submission. With the upcoming transition from IEC 60601-1 3rd Edition to 4th edition, a change which the CSS was already designed in compliance with, the queue to get devices into TUV substantially lengthened, exceeding what we originally allocated for an intended October FDA submission. This is pushing our timeline further back, but I have complete confidence in the engineers at CVR and the quality of the product they designed. With their focus on developing a product that is first and foremost safe, I believe that we will progress smoothly through the TUV testing schedule without delay. With the majority of our De Novo documentation finalized and current clinical trial numbers exceeding the requirements anticipated by our industry-leading regulatory consultants, we are still targeting an end of Q4 submission. However, this is contingent on external forces and is out of CVR's control, though all key stakeholders are working tirelessly to expedite the process.

CVR also announces the intention to submit to Health Canada for a Canadian Medical Device License (MDL), which would provide approval for sales of the CSS into Canada, forthwith upon submitting to the FDA for market clearance. Obtaining the ability to distribute the CSS into Canada would open up one of the largest global economies, with diagnostic imaging representing 21% of their \$6.7 billion medical device market.

Peter Bakema, CEO and Board Chairman, elaborates on the decision to launch into Canada in the near term, "It only makes sense that we continue our momentum with submitting to the FDA, leveraging both relational and geographic advantages. With the submission requirements mirroring most of the EU Technical dossier we will be able to advance the pace of global availability."

About CVR Medical

CVR Medical Corp. is a healthcare company that operates in the medical device industry focused on the commercialization of its disruptive, proprietary Carotid Stenotic Scan (CSS). The CSS device is a diagnostic tool that encompasses subsonic, infrasonic, and low frequency sound wave analysis technology. The CSS is a patented device designed to detect and measure carotid arterial stenosis which significantly increases the risk of stroke. CVR is currently in pivotal clinical trials in preparation for its planned submission to the FDA. CVR is led by an experienced and

proven team of professionals with extensive healthcare, medical device, international expansion, regulatory and sales experience. CVR Medical trades on the TSX Venture Exchange under the symbol CVM. Additional information regarding the Company can be found in our recent filings with the SEDAR as well as the information maintained on our website at www.cvrmed.com

ON BEHALF OF THE BOARD:
(signed) "Peter Bakema"
CEO, President & Chairman

For further information contact:
Peter Bakema, CEO, President and Chairman
Email: info@cvrmed.com
or
Marc S. Lubow.
Vice President Capital Markets, Director / Investor Relations
marclubow@cvrmed.com

This press release contains forward-looking information that involves various risks and uncertainties regarding future events related to the Joint Venture. Such statements are subject to risks and uncertainties that may cause actual results, performance or developments to differ materially from those contained in the statements and are not guarantees of future performance of the Company. No assurance can be given that any of the events anticipated by the forward-looking statements will occur or, if they do occur, what benefits the Company will obtain from them. These forward-looking statements reflect management's current views and are based on certain expectations, estimates and assumptions which may prove to be incorrect. A number of risks and uncertainties could cause our actual results to differ materially from those expressed or implied by the forward-looking statements, including: (1) a downturn in general economic conditions in North America and internationally, (2) the inherent uncertainties and speculative nature associated with commercialization of technology and the practice of medicine, (3) a change in health regulations, (4) any number of events or causes which may delay or cease commercialization and development of the Joint Venture, (5) the risk that the Company or the Joint Venture does not execute its business plan, (6) inability to retain key employees, (7) inability to finance operations and growth, and (8) other factors beyond the Company's control. These forward-looking statements are made as of the date of this news release and, except as required by law, the Company assumes no obligation to update these forward-looking statements, or to update the reasons why actual results differed from those projected in the forward-looking statements.

THE TSX VENTURE EXCHANGE INC. HAS NEITHER APPROVED NOR DISAPPROVED THE CONTENTS OF THIS PRESS RELEASE. NEITHER THE TSX VENTURE EXCHANGE NOR ITS REGULATION SERVICES PROVIDER (AS THAT TERM IS DEFINED IN THE POLICIES OF THE TSX VENTURE EXCHANGE) ACCEPTS RESPONSIBILITY FOR THE ADEQUACY OR ACCURACY OF THIS RELEASE.

Peter Bakema
CVR Medical Corp.
+1 734-718-5115
[email us here](#)

This press release can be viewed online at: <http://www.einpresswire.com>

Disclaimer: If you have any questions regarding information in this press release please contact the company listed in the press release. Please do not contact EIN Presswire. We will be unable to assist you with your inquiry. EIN Presswire disclaims any content contained in these releases. © 1995-2018 IPD Group, Inc. All Right Reserved.