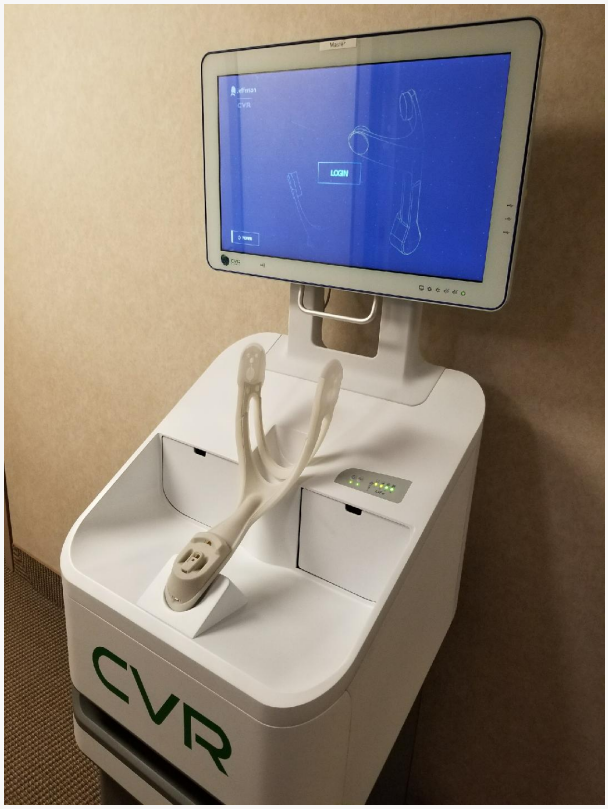
CVR & U.S. FDA: A Meeting of the Minds

VANCOUVER, BC, CANADA, May 9, 2018 /EINPresswire.com/ -- Concludes De Novo Pathway Best Suited



CVR - CSS Device

CVR Medical Corp. (CVM.V) (TSXV: CVM) (FRANKFURT: B3BN) (OTCQB: CRRVF) ("CVR Medical") announces the receipt of official meeting minutes for their Pre-Submission meeting on March 23, 2018 with the U.S. Food and Drug Administration (FDA) regarding the Carotid Stenotic Scan (CSS) device and it's upcoming FDA submission for market release. Attendees of the meeting included CVR management, regulatory consultant's Duval & Associates, and key reviewers from the FDA. The purpose of the meeting was to receive feedback and define the necessary regulatory pathway, clinical trial substantiation requirements, and device testing.

Based on prior communication with the FDA and input provided by key regulatory advisors, CVR had considered the potential for either a 510k, De Novo, or PMA submission; with the De Novo being the preferred pathway. During the meeting these topics were discussed and in follow-up communication the FDA team stated the CSS was sufficiently different from other devices on the market today to decide the De Novo pathway was best suited, which is designed for low to moderate risk novel devices.

CVR COO Tony Robinson states, "The pre-submission meeting went as expected. The CVR leadership team had quality dialog with the FDA reviewers, resulting in meaningful clarity and understanding of the project for both sides. We truly value the FDA's input, alleviating much of the concern stemming from questions about the direction and pathway of the project. Upon further discussion, we understand the clinical trial requirements will fall within the previously expected range. Altogether, I believe we align with the FDA on this undertaking, and CVR is poised for our upcoming submission and subsequent approval."

Mark DuVal, President of Duval & Associates, who was also present at the meeting stated, "Communications with FDA regarding the CSS device to date have been very collaborative and responsive. Our firm believes that the De Novo program will provide the most efficient pathway to US commercialization of the CSS device. We also believe the FDA has accepted our argument that the CSS represents a lower risk device than standard Doppler Ultrasound. This will reduce data requirements. Now we move into a phase of offering FDA proposed 'special controls' which are tests we propose to conduct to address these risks, albeit low risks, of using this device."

CVR Chief Executive Officer, Peter Bakema, expands upon the FDA's decision as it applies to the

overall project, “While every member of our team and board are excited about the FDA’s observation that our CSS Device has no predicate, due to the continual evolution of this project, this exciting development does require us to extend our previously stated guidance regarding our targeted submission date. With the De Novo process and associated factors comes a much higher level of documentation and testing requirements. Due to these vital elements we feel it necessary to extend our projected submission timeline another 60 to 90 days. Both myself and team have already taken the actions to mitigate this addition to the timeline. We anticipate an end of Q3 submission, and will update our timeline as we move closer.”

For additional information on the organization, leadership, and current news please visit the company website www.CVRMed.com

About CVR Medical

CVR Medical is a company that is involved in an equal parts joint venture with CVR Global Inc. (the "Joint Venture"). The Joint Venture operates in the medical industry focused on the commercialization of a proprietary subsonic, infrasonic, and low frequency sound wave analysis technology and has patents to a diagnostic device designed to detect and measure carotid arterial stenosis. CVR Medical is managed by a proven technical team. CVR Medical trades on the TSX Venture Exchange under the symbol CVM.

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

For further information contact:
Peter Bakema, CEO, President and Director
Telephone: (734) 718-5115
Email: info@cvrmed.com
or
Marc S. Lubow.
Vice President Capital Markets, Investor Relations
marclubow@cvrmed.com
Telephone: (403) 262-9888
or
Brisco Capital Partners Corp.
Scott Brisco, President
Telephone: (403) 262-9888

Peter Bakema
CVR Medical Corp.
734-718-5115
email us here
