



# CVR MEDICAL REPORTS POSITIVE INTERIM RESULTS FROM ONGOING PIVOTAL TRIAL WITH CSS DEVICE

*Preliminary Analysis Demonstrates CSS Device Has To Date Exceeded Expectations for Specificity and Sensitivity Compared to Duplex Doppler Ultrasound*

VANCOUVER, BRITISH COLUMBIA, CANADA, August 20, 2018 /EINPresswire.com/ -- VANCOUVER, BC / August 20th, 2018 / 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 advisory staff member Dr. Phillip J. Bendick, PhD, has released an internal report summarizing data from the pivotal clinical trials for the Carotid Stenotic Scan (CSS) devices in use at Thomas Jefferson University Hospital. In alignment with the previous report released by Dr. Bendick in September 2017, this preliminary report views the initial batch of data points collected within the trial as successful for the substantiation of the device's value and efficacy. Though only a partial snapshot of the data (with the trial ongoing), the improvements made to the CSS prior to launch of the pivotal clinical trials has generated enhanced functionality within the clinical setting.

The CSS Device is being evaluated in a multi-center pivotal clinical trial to evaluate the system's specificity and sensitivity for detecting carotid artery disease, compared to the current gold standard – duplex Doppler ultrasound.

Dr. Bendick states, "The early results of the first 144 patients enrolled in the CSS pivotal trial have shown excellent overall accuracy [...] these initial results demonstrate the efficacy of the CSS as a tool to detect and guide the appropriate management of clinically important carotid artery disease in order to reduce stroke risk."

"This report further validates the advancements implemented by CVR prior to the launch of our pivotal trials," said Peter Bakema, CVR CEO. "All along we have aimed to arm the clinician with a tool that is not only accurate, but seamlessly translates to improved care for his or her patients. Every aspect of the CSS, from the user interface to the streamlined cart, embodies this principle. This preliminary report reinforces our previously stated commitment to deliver a product with greater than 85% sensitivity level."

Additionally, due to the current extended lead time for mandatory electrical safety testing, CVR has extended its anticipated CSS FDA submission target to October 2018.

Carotid Stenotic Scan Pivotal Trial Internal Data Analysis: Data Summary with Patient Edits\*  
By: Phillip J. Bendick, PhD

Location: Thomas Jefferson University Hospital  
Primary Investigator: Dr. David Whellan

Number of Samples Evaluated (Vessels): N=255\*\*  
Right 129  
Left 126

True Negative (<50%)

Right 10  
Left 15  
Total 25

True Positive (>50%)

Right 3  
Left 6  
Total 9

False Negative

Right 0  
Left 2  
Total 2

False Positive

Right 6  
Left 3  
Total 9

False Positive / Negative Causes

Incorrect Sensor Array Placement 4  
Excessive Noise (Internal) 2  
Hardware Error 3  
Unknown 2  
Total 11

Given These Results-

Specificity 25/236 96%

Sensitivity 19/21 90%

Overall Accuracy 44/255 96%

\* Patient exclusions (33 vessels): Prior carotid endarterectomy, prior carotid stent, prior neck surgery, severe heart disease.

\*\* Vessels with No Reading (NR) or poor Quality of Placement (QOP) – 38 (Most of these were on Device 7)

CAUTION: FOR INVESTIGATIONAL USE ONLY. This device is not yet cleared or approved for use in humans by the Food and Drug Administration.

#### 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 CSS Device. The CSS device is a diagnostic tool that encompasses subsonic, infrasonic, and low frequency sound wave analysis technology. The CSS Device is a patented device designed to detect and measure carotid arterial stenosis. 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](http://www.cvrmed.com)

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

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