

# Ventripoint Provides Update on Clinical Studies

NEWS RELEASE BY VENTRIPOINT DIAGNOSTICS LTD.

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Toronto, Ontario – TheNewswire – September 15, 2021 – Ventripoint Diagnostics Ltd. ("Ventripoint" or the "Company"), (TSXV:VPT); (OTC:VPTDF) has provided an update on clinical studies using the VMS+ 3.0.

### Ventripoint Overview: A Revolutionary Way to View and Analyze the Heart

Ventripoint is an industry leader in the application of ultrasound AI (artificial Intelligence) for heart imaging. The company's VMS+ 3.0 technology offers a proven, patented, non-invasive AI solution for 3D visualization of all four chambers of the heart, providing a pivotal new diagnostic tool for aiding cardiologists to combat cardiovascular disease and sustain heart health in both adults and children. VMS+3.0 delivers a faster, more precise and economical way to view and analyze the heart, providing results equivalent to more expensive and time-consuming MRI. These advantages also allow for faster, more frequent monitoring of patients.

### The VMS™ Technology

VMS+ (Ventripoint Medical System Plus) 3.0 marries the high-resolution of cardiac MRI (Magnetic Resonance Imaging) and ease of use of ultrasound with the power of Ventripoint's proprietary KBR (Knowledge-Based Reconstruction) AI technology. KBR enables physicians to construct a precise 3D model of the heart and calculate volumes and ejection fractions for all chambers of the heart with an accuracy equivalent to MRI using standard ultrasound images obtained using any cardiac ultrasound machine such as General Electric, Phillips, Siemens, etc.

### Planned and Ongoing Clinical Studies

The Company has twelve clinical projects underway or being planned. This shows the innovative nature of the VMS+3.0 in enabling clinicians to study a variety of heart

problems by analyzing the whole heart for the first time. All these studies are being funded through institutional sponsorships or grants. The Company is providing training for research staff and logistical support for these ground-breaking studies conducted by leading cardiologists. Below is brief description of the five projects currently underway.

A more comprehensive description of each clinical project will be available on the Company's website shortly. The other seven studies will address, single-ventricle, hypertension, Duchenne muscular dystrophy, acute COVID-19, long-haul COVID-19, COVID-19 in elite athletes and surgical planning in valve replacements. The Company will provide details on these studies when they have been approved by the host institutions.

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#### 1. Normal and Abnormal Maternal Heart Function during Pregnancy

The Company is supporting a world-first study on maternal cardiovascular changes during pregnancy. A recent review\* stated, "Profound haemodynamic changes, such as a 50% increase in cardiac output, place an added burden on the maternal cardiovascular system during pregnancy and can provoke new-onset or an exacerbation of existing cardiovascular disease. Cardiovascular disease complicates 1-4% of pregnancies and is more common in women with hypertensive disorders, which is the leading cause of maternal death". There are 4 million births a year in the United States and 8 million in Europe and maternal hypertensive deliveries has been increasing steadily for decades.\*\* They are estimated to represent 10% of births according to the CDC. It is hard to imagine but the changes in a mother's heart during pregnancy have never been studied in detail.

A study of the changes in vascular and ventricular function in healthy pregnant women and those with underlying cardiovascular disease is beginning at a major heart center. The VMS+3.0 will be used to perform repeated heart assessments in this study and will allow for quick and accurate measurements in this groundbreaking study of women's health. The study has been awarded funding by a national granting agency.

\* (Ramlakhan et al, Pregnancy and cardiovascular disease. Nat Rev Cardiol 17, 718–731 (2020). <https://doi.org/10.1038/s41569-020-0390-z>)

**\*\*<https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pregnancy-complications-data.htm>**

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## 2. Congenital Heart Defects with Septal Defects

It is estimated 1.35 million babies are born with Congenital Heart Defects (CHD) each year.\* The American CDC (**<https://www.cdc.gov/ncbddd/heartdefects/data.html>**) estimates there are 1 million children and young adults and 1.4 million adults living with CHD in the United States. In 2013, hospital costs for this population of individuals with cardiovascular defects were about USD\$6.1 billion.

Atrial and Ventricular Septal Defects (ASD and VSD) are the most common forms of Congenital Heart Disease (CHD), worldwide\*. A septal defect is a hole in the heart wall (septum) that divides the left and right chambers of the heart. This causes oxygenated blood to leak back into the right side of the heart from the left side resulting in damage to pulmonary circulation and overworking the heart and lungs. The study will pioneer a novel minimally-invasive procedure to seal the hole in ASD patients and the VMS+3.0 will be used to monitor the efficacy of the procedure by measuring the remodeling of the atria to normal anatomy and function.

\* van der Linde et al, Birth Prevalence of Congenital Heart Disease Worldwide: A Systematic Review and Meta-Analysis, Journal of the American College of Cardiology, Volume 58, Issue 21, 2011, Pages 2241-2247, ISSN 0735-1097, **<https://doi.org/10.1016/j.jacc.2011.08.025>**.

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## 3. LA Enlargement as an Earlier Indicator of Heart Failure with Diastolic Dysfunction

Heart failure is a global health concern affecting at least 26 million people worldwide and is increasing in prevalence as populations age and become more affluent.\* It is estimated that 30% to 90% of patients with heart failure have diastolic dysfunction or stiffening of the heart.\*\* Left atrial enlargement (LAE) correlates to diastolic dysfunction\*\* (also known as heart failure with preserved ejection fraction,” or HFpEF) and is a marker of severity of mitral stenosis and regurgitation as well as a risk factor for atrial arrhythmias\*\*\*. LAE may be an early indicator of HFpEF. Lung congestion due to HFpEF often has a rapid onset with difficulty to breathe. This study will determine if a simple way to measure LAE would enable earlier identification of patients at risk for heart failure.

\*Savarese et al, Global Public Health Burden of Heart Failure. *Card Fail Rev.* 2017 Apr;3(1):7-11. doi: 10.15420/cfr.2016:25:2. PMID: 28785469; PMCID: PMC5494150.

\*\*Blume et al, Left atrial function: Physiology, assessment, and clinical implications. *European Journal of Echocardiography*, 12, 421–430. doi:10.1093/ejechocard/jeq175

\*\*\*Brucks et al, Contribution of left ventricular diastolic dysfunction to heart failure regardless of ejection fraction. *Am J Cardiol.* 2005 Mar 1;95(5):603-6. doi: 10.1016/j.amjcard.2004.11.006. PMID: 15721099.

\*\*\*\*Leung et al, Echocardiographic evaluation of left atrial size and function: Current understanding, pathophysiologic correlates, and prognostic implications. *American Heart Journal*, 156(6), 1056–1064. doi:10.1016/j.ahj.2008.07.021

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#### 4.RA and RV Enlargement as an Indicator of Tricuspid Valvular Dysfunction

Right atrial (RA) volume is a marker of right ventricular (RV) diastolic dysfunction and severity of tricuspid regurgitation or stenosis. There is surprisingly little information, and limited tools validated for accurately measuring right atrial and ventricular dimensions and function. The VMS+3.0 is a simple and reliable way of measuring RA and RV volumes

and is being used to study children with valvular disease to better characterize the severity of the valvular disease.

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5.Benefits of VMS+3.0 for Determining Optimal Point for Pulmonary Valve Replacement (PVR) in Young Adults with Tetralogy of Fallot

A recent review\* in 2020 stated, “The benefits of pulmonary valve replacement (PVR) for pulmonary insufficiency in patients with repaired tetralogy of Fallot are still incompletely understood, and optimal timing remains challenging”. This study will review the experience of one center, which has used the VMS+ to assess over 500 patients before and after PVR. The ease of use of the VMS+ has enabled more frequent monitoring of the RV and expected to show the optimal RV volume for PVR to achieve the best outcome.

\*(Van den Eynde et al, Pulmonary Valve Replacement in Tetralogy of Fallot: An Updated Meta-Analysis. Ann Thorac Surg. 2020 Dec 27:S0003-4975(20)32173-1. doi: 10.1016/j.athoracsur.2020.11.040. Epub ahead of print. PMID: 33378694)

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