

# **Ventripoint Diagnostics Announces U.S. FDA 510(k) Clearance for VMS+™ 4.0 Automated Radiological Image Processing Software/System**

**Toronto, Ontario (February 27, 2025)** - Ventripoint Diagnostics Ltd. ("**Ventripoint**" or the "**Company**"), (TSXV:VPT; OTC:VPTDF) is pleased to announce that it has received U.S. Food and Drug Administration ("**FDA**") 510(k) clearance for the VMS+™ 4.0 Automated Radiological Image Processing Software/System.

This latest advancement of Ventripoint's proprietary technology, VMS+ 4.0, delivers a number of significant enhancements including:

- AI-assisted automated point placement to improve user workflow efficiency
- Magnet-free sensors enabling more efficient pairing and improved workflow
- User tools to assist with analysis of the cardiac views
- Enhanced visualization tools
- Measurements generated from the 3D wire mesh:
  - ED Volume,
  - ED Volume Index,
  - ES Volume,
  - ES Volume Index,
  - Ejection Fraction,
  - Cardiac Output,
  - Cardiac Index,
  - Stroke Volume,
  - Stroke Volume Index.
- Reporting of all measurements and derived parameters

In addition, the introduction of the magnet-free sensors to VMS+ 4.0 enables VMS+ to be used for patients with cardiac pacemakers. There are an estimated 3 million people in the U.S. with cardiac pacemakers who are unable to be imaged with MRI and who depend on echocardiography to monitor their heart disease. VMS+ is unique in its ability to report volumes and ejection fractions for all four chambers of the heart with MRI levels of accuracy.

The VMS+ 4.0 system connects to standard echocardiography machines, the most widely used cardiac imaging technology globally. The system uses Ventripoint's proprietary Knowledge Based Reconstruction technology to create 3D images of the heart and calculates volumes and ejection fraction for all 4 cardiac chambers with accuracy equivalent to MRI. The system can reduce the need for MRI in children and adults.

"Ventripoint has deep experience in the application of AI to echocardiography and this FDA clearance is the culmination of more than two years of research and

development,” said Ventripoint President and CEO, Hugh MacNaught. “We are thrilled with the opportunity to offer U.S. hospitals an efficient and effective, non-invasive heart-imaging tools available. AI enhanced echocardiograms are a fast, affordable and accessible tool for diagnosis and monitoring of the growing numbers of cardiac patients in America and worldwide.”

VMS+ 4.0 has already received regulatory clearance in other key markets such as the E.U., U.K. and Canada making this latest version of VMS+ available to the global community. Earlier versions of Ventripoint’s scanning technology received FDA, Health Canada and E.U. regulatory approvals and are being used by leading hospitals in the U.S., E.U., U.K. and Canada.

### **About Ventripoint Diagnostics Ltd.**

Ventripoint is an industry leader in the application of AI (Artificial Intelligence) to echocardiography. Ventripoint's VMS+ products are powered by its proprietary Knowledge Based Reconstruction technology, which is the result of a decade of development and provides accurate volumetric cardiac measurements equivalent to MRI. This affordable, gold-standard alternative allows cardiologists greater confidence in the management of their patients. Providing better care to patients serves as a springboard and basic standard for all of Ventripoint's products that guide our future developments. In addition, VMS+ is versatile and can be used with all ultrasound systems from any vendor supported by regulatory market approvals in the U.S., Europe, and Canada.

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### **Forward Looking Statements**

This news release contains forward-looking statements and forward-looking information within the meaning of applicable securities laws. The use of any of the words "expect", "anticipate", "continue", "estimate", "objective", "ongoing", "may", "will", "project", "should", "believe", "plans", "intends" and similar expressions are intended to identify forward-looking information or statements. The forward-looking statements and information are based on certain key expectations and assumptions made by the Company. Although the Company believes that the expectations and assumptions on which such forward-looking statements and information are based are reasonable, undue reliance should not be placed on the forward-looking statements and information because the Company can give no assurance that they will prove to be correct.

Since forward-looking statements and information address future events and conditions, by their very nature they involve inherent risks and uncertainties. Actual

results could differ materially from those currently anticipated due to a number of factors and risks. Factors which could materially affect such forward-looking information are described in the risk factors in the Company's most recent annual management's discussion and analysis that is available on the Company's profile on SEDAR at [www.sedar.com](http://www.sedar.com). Readers are cautioned that the foregoing list of factors is not exhaustive. The forward-looking statements included in this news release are expressly qualified by this cautionary statement. The forward-looking statements and information contained in this news release are made as of the date hereof and the Company undertakes no obligation to update publicly or revise any forward-looking statements or information, whether as a result of new information, future events or otherwise, unless so required by applicable securities laws.

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