Conavi Medical Announces FDA 510(k) Clearance of its Next-Generation Hybrid IVUS-OCT System for Intravascular Imaging

- First co-registered and co-aligned IVUS-OCT Platform for Intravascular Imaging
- Company Positioned for U.S. Commercial Launch in a Growing Intravascular Imaging Market Estimated at Over $1 Billion

TORONTO, April 20, 2026 -- Conavi Medical Corp., a commercial stage medical device company focused on designing, manufacturing, and marketing imaging technologies to guide common minimally invasive cardiovascular procedures, today announced that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for its next-generation hybrid imaging system, designed to deliver a more complete assessment of coronary anatomy within a single workflow. The milestone positions the Company to initiate its U.S. commercial launch expected in calendar H2 2026 and to expand its hybrid intravascular imaging technology.

Conavi's next-generation hybrid imaging system integrates intravascular ultrasound (IVUS) and optical coherence tomography (OCT) into a single platform. These technologies together enable physicians to visualize both deep vessel structures (IVUS) and high-resolution surface detail (OCT) in real time. It is designed to support physician decision making and streamline workflows.

"FDA clearance of our next-generation hybrid imaging system marks a pivotal moment for Conavi as we transition into commercial launch in the U.S.," said Thomas Looby, Chief Executive Officer of Conavi Medical. "We believe hybrid IVUS-OCT imaging represents the next evolution in intravascular imaging, bringing together IVUS and OCT into a single system to give a complete picture of the vessel. With this clearance, we are focused on executing our U.S. commercial launch expected in calendar H2 2026, supporting physician decision-making during these procedures, and driving adoption in leading U.S. centers. This clearance reflects years of focused work by an exceptional team across engineering, clinical, regulatory, and operations, and would not have been possible without the trust of our clinical investigators, the commitment of our manufacturing and supply partners, and the continued support of our shareholders."

"Hybrid IVUS-OCT imaging has the potential to meaningfully enhance how we approach complex coronary interventions," said Dr. Megha Prasad, Interventional Cardiologist at New York-Presbyterian Hospital. "The ability to simultaneously evaluate plaque composition, vessel size, and stent expansion in a single pullback can support procedural decision-making and workflow efficiency. Technologies like Conavi's next-generation hybrid system are helping move the field toward more precise, image-guided care, and I look forward to using it regularly in my practice."

Advancing the Standard of Care in Intravascular Imaging
Intravascular imaging is increasingly recognized as a critical tool in percutaneous coronary intervention (PCI), with growing clinical evidence demonstrating improved outcomes when imaging is used to guide stent sizing and placement. However, adoption remains underpenetrated globally, in part due to workflow complexity and the need to use multiple imaging systems.

Conavi's next-generation hybrid imaging system addresses these needs by:

- Enabling simultaneous, co-registered IVUS and OCT imaging in a single pullback
- Providing lesion and stent analysis tools that incorporate insights from both imaging modalities
- Enabling streamlined catheter connection workflow designed for ease of use
- Featuring a catheter design focused on enhanced deliverability
- Eliminating the need for multiple imaging systems

As healthcare systems continue to prioritize precision, efficiency, and outcomes, intravascular imaging has become one of the fastest-growing segments in interventional cardiology.

Large and Growing Market Opportunity
The intravascular imaging market, including IVUS and OCT technologies, represents a significant and growing segment within interventional cardiology, driven by increasing adoption of image-guided PCI procedures. The global market opportunity for coronary intravascular imaging is estimated to exceed $4 billion annually, with IVUS and OCT penetration currently at 30–40% of eligible procedures and continuing to expand.

Growth is being driven by:

- Increasing adoption of image-guided PCI procedures
- Expanding clinical evidence supporting improved patient outcomes
- Greater focus on optimizing stent placement and reducing repeat interventions
- Continued integration of AI and advanced imaging technologies into clinical workflows

Commercial Readiness and Launch Strategy
Following FDA clearance, Conavi is actively preparing for U.S. commercialization. The Company expects to initiate a limited

market release in select U.S. centers in the second half of calendar 2026.

About Conavi Medical
Conavi Medical is focused on designing, manufacturing, and marketing imaging technologies to guide common minimally invasive cardiovascular procedures. Its patented next-generation hybrid imaging system is the first system to co-register and co-align intravascular ultrasound (IVUS) and optical coherence tomography (OCT) imaging beams to enable simultaneous hybrid imaging of coronary arteries. The next-generation hybrid imaging system has 510(k) clearance from the U.S. Food and Drug Administration. For more information, visit http://www.conavi.com/.

Notice on forward-looking statements:
This press release includes forward-looking information or forward-looking statements within the meaning of applicable securities laws regarding the Company and its business, which may include, but are not limited to, statements with respect to the commercialization and commercial launch of Conavi's next-generation hybrid imaging system and the timing thereof, the sufficiency of Conavi's resources to achieve such commercial launch, the global market opportunity for coronary intravascular imaging (including for IVUS and OCT), the continued growth in adoption of and in the clinical validation and guideline support for intravascular imaging and the ability of Conavi's next-generation hybrid imaging system to meet market needs. All statements that are, or information which is, not historical facts, including without limitation, statements regarding future estimates, plans, programs, forecasts, projections, objectives, assumptions, expectations or beliefs of future performance, are "forward-looking information or statements". Often but not always, forward-looking information or statements can be identified by the use of words such as "shall", "intends", "anticipate", "believe", "plan", "expect", "intend", "estimate" or any variations (including negative variations) of such words and phrases, or state that certain actions, events or results "may", "might", "can", "could", "would" or "will" be taken, occur, lead to, result in, or, be achieved. Such statements are based on the current expectations and views of future events of the management of the Company. They are based on assumptions and subject to risks and uncertainties. Although management believes that the assumptions underlying these statements are reasonable, they may prove to be incorrect. The forward-looking events and circumstances discussed in this release, may not occur and could differ materially as a result of known and unknown risk factors and uncertainties affecting the Company, including, without limitation, those listed in the "Risk Factors" section of the annual information form of the Company dated February 26, 2026 (available on the Company's profile at www.sedarplus.ca). Although the Company has attempted to identify important factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements, there may be other factors that cause actions, events or results to differ from those anticipated, estimated or intended. Accordingly, readers should not place undue reliance on any forward-looking statements or information. No forward-looking statement can be guaranteed. Except as required by applicable securities laws, forward-looking statements speak only as of the date on which they are made and the Company does not undertake any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise.

No regulatory authority has approved or disapproved the content of this press release. Neither the TSX Venture Exchange nor its Regulatory Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this press release.

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