Medtronic News

Medtronic announces co-promotion agreement with CathWorks, with path toward acquisition

- Partnership underscores Medtronic's commitment to investing in innovative technologies that support physicians and patients from diagnosis to treatment
- CathWorks' FFRangio® System provides diagnostic and physiologic information through artificial intelligence to potentially disrupt traditional FFR and revolutionize the management of coronary artery disease

DUBLIN and KEFAR SAVA, Israel, July 12, 2022 /PRNewswire/ -- Medtronic plc (NYSE:MDT), a global leader in healthcare technology, today announced it has entered into a strategic partnership agreement with CathWorks, a privately held company headquartered in Kefar Sava, Israel, which aims to transform how coronary artery disease (CAD) is diagnosed and treated.

As part of the agreement, Medtronic will invest up to$75 million and immediately begin co-promotion of CathWorks' FFRangio® System in the U.S., Europe and Japan, where it is commercially available. As part of a separate agreement, Medtronic will have the option to acquire CathWorks once certain undisclosed milestones are met. CathWorks will also have the right to compel Medtronic to acquire the company if Medtronic chooses not to exercise its option. The acquisition option agreement will expire in July of 2027, with an estimated acquisition of up to $585 million and potential undisclosed earn-out payments post-acquisition. Medtronic has held a minority investment in CathWorks since 2018.

Fractional flow reserve (FFR) is a diagnostic technique that evaluates the physiologic impact of coronary artery stenosis, making it an important part of the decision-making process when managing patients with CAD. While FFR is an important diagnostic tool, supported by strong clinical evidence,[1] the nature of traditional FFR — which requires invasive measurements with wires and stimulation with hyperemic agents— has resulted in its underutilization. In contrast to traditional FFR, the FFRangio System combines artificial intelligence (AI) and advanced computational science to obtain quick and reliable FFR values from routine angiograms (X-rays), eliminating the need for drug stimulation and invasive pressure wires.

"Data and AI-enabled technologies have been shown to drive improved workflow and patient outcomes across the healthcare ecosystem. In cardiology specifically, these new advances in technology provide clinicians with the opportunity to gain additional information to improve and evolve the diagnosis and treatment of patients with CAD," said Jason Weidman, senior vice president and president of the Coronary & Renal Denervation business, which is part of the Cardiovascular Portfolio at Medtronic. "We are excited to partner with CathWorks to offer the FFRangio system to our customers. We believe strongly in the potential of the technology and are committed to strengthening our relationship with CathWorks to provide new, innovative technologies and solutions from diagnosis to treatment."

Backed by robust clinical evidence, FFRangio has demonstrated excellent diagnostic performance compared to wire-based FFR. According to clinical data published in the *Journal of the American College of Cardiology (JACC): Cardiovascular Interventions*, FFRangio showed diagnostic accuracy of 93%, sensitivity of 91%, and specificity of 94%.[2] This non-invasive technology has the potential to disrupt and expand traditional FFR segments. Traditional FFR today is an approximate $750 million product segment that is growing at low-double digits.

"CathWorks has been looking for the right partner to help us expand the reach of the FFRangio system globally," said Ramin Mousavi, president and chief executive officer of CathWorks. "Medtronic not only brings the strength of its commercial team to CathWorks, but a reputation of investing and defining new opportunities to revolutionize care. I am excited about the possibilities ahead as we partner with Medtronic to expand the use of our technology to the U.S., Japan and Europe."

Financial Highlights

The co-promotion agreement is expected to be neutral to Medtronic's fiscal year 2023 GAAP and adjusted earnings per share

and neutral to accretive thereafter.

About CathWorks

CathWorks is the leader in digital health innovations that can improve the lives of patients globally. The CathWorks FFRangio® System combines artificial intelligence and advanced computational science, transforming how cardiovascular disease is diagnosed and treated. The FFRangio System obtains physiologic information from routine angiograms, eliminating the need for drug stimulation and invasive pressure wires. It provides physicians with quick and reliable intraprocedural FFR values for the entire coronary tree that is practical for every patient. For more information on CathWorks, visit www.cath.works and follow @CathWorks on Twitter and LinkedIn.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered inDublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

1. Bernard De Bruyne, M.D., Ph.D., Nico H.J. Pijls, M.D., Ph.D., Bindu Kalesan, M.P.H.,Emanuele Barbato, M.D., Ph.D., Pim A.L. Tonino, M.D., Ph.D., Zsolt Piroth, M.D., Nikola Jagic, M.D., Sven Möbius-Winkler, M.D., Gilles Rioufol, M.D., Ph.D., Nils Witt, M.D., Ph.D., Petr Kala, M.D., Philip MacCarthy, M.D., Thomas Engström, M.D., Keith G. Oldroyd, M.D., Kreton Mavromatis, M.D., Ganesh Manoharan, M.D., Peter Verlee, M.D., Ole Frobert, M.D., Nick Curzen, B.M., Ph.D., Jane B. Johnson, R.N., B.S.N., Peter Jüni, M.D., andWilliam F. Fearon, M.D., for the FAME 2 Trial Investigators. Fractional Flow Reserve–Guided PCI versus Medical Therapy in stable coronary disease. The New England Journal of Medicine 2012; 367:991-1001DOI: 10.1056/NEJMoa1205361
2. Witberg G, De Bruyne B, Fearon WF, Achenbach S, Engstrom T, Matsuo H, et al. . Diagnostic performance of angiogram-derived fractional flow reserve: a pooled analysis of 5 prospective cohort studies. JACC Cardiovasc Interv. (2020) 13:488–97. 10.1016/j.jcin.2019.10.045

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