

FAME 2 Published in the New England Journal of Medicine, Volcano participates in the \$84M NIH-Sponsored ISCHEMIA Trial

The Associated Press

Volcano Corporation (NASDAQ: VOLC) a worldwide leader in precision guided therapy tools, today celebrated the publication of the results of the FAME 2 trial in the New England Journal of Medicine (NEJM). Volcano also announced participation in the next major international functionally-guided study-ISCHEMIA that will include the newest PrimeWire@ PRESTIGE PLUS Pressure Guidewires.

Ever since the COURAGE trial demonstrated that not every patient entering the cath lab benefits from stenting, the interventional cardiology community has been exploring more precise ways to identify which patients will benefit most from PCI, and which patients should instead be treated with optimal medical therapy (OMT) alone. The initial FAME study published in the NEJM showed that PCI outcomes can be improved by guiding a stent strategy using Fractional Flow Reserve (FFR) instead of angiography alone as was practiced in COURAGE. The results of the FAME study showed that the number of vessels that actually needed treatment was dramatically less than previously thought, and therefore reduced the complexity of the initial angiographic diagnosis.

FAME 2 (Fractional Flow Reserve-Guided PCI vs. Medical Therapy in Stable Coronary Disease) is the second FFR-guided randomized clinical trial to be published in the NEJM. It demonstrates that using stents to treat patients with proven ischemia by FFR does in fact deliver better outcomes than OMT alone in the combined endpoint of death, myocardial infarction (MI) and urgent revascularization. It is important to note that the FAME 2 trial was halted early by the Independent Data Safety Monitoring Board because it determined it was unethical to continue enrolling patients in the medical therapy only arm due to the increased risk of these significant adverse events.

"The FAME 2 study is important because it shows COURAGE and angiography alone are not enough. FAME 2 demonstrates that when deciding between OMT and interventional therapy you need to know if there is ischemia. This will help lead to the right therapy for the right patient," commented Scott Huennekens, President & CEO of Volcano Corporation. "With the FAME 2 data in hand, and a few moments in the cath lab to perform FFR, interventional cardiologists can confidently say to their patients that PCI is the right personalized approach for them, and have the FFR value to prove it. Having the data now published in the New England Journal is a testament to the hard work of the investigators and the quality of the study design and execution." FAME 2 showed that patients receiving PCI with proven ischemia by FFR had 66% fewer primary endpoint events including death, MI and urgent vascularization's than those patients treated with medical therapy alone (percentage of patients who had a primary endpoint event: 4.3% in the PCI group

and 12.7% in the medical-therapy group; hazard ratio with PCI, 0.32; 95% confidence interval [CI], 0.19 to 0.53; $P < 0.001$).

The Registry arm also showed that patients with a negative FFR suggesting absence of ischemia did very well being treated with just medical therapy and no further intervention (primary endpoint event rate of 3.0).

"The evidence continues to mount that using the physiology or the functional evaluation of a lesion is better than relying on angiography alone," added Joe Burnett, Executive Vice President and Physiology Business Unit Leader for Volcano. "We are all striving to improve outcomes and control costs at the same time, which means we need to make every device count. Tools available today like FFR and IVUS provide objective evidence to help make those critical decisions.

Angiography guided PCI is giving way to Functional PCI to assess, guide and document each patient's unique episode of care. This is why we are thrilled to provide our FFR and IVUS technology to the ISCHEMIA investigators for use in the next landmark stable coronary disease trial." The International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) is a randomized controlled trial that will study 8,000 patients with stable ischemic heart disease (SIHD) and moderate to severe ischemia. Patients will be randomized between invasive revascularization therapies including PCI and more conservative treatment focused on optimal medical therapy.

The study, funded by one of the largest grants ever awarded by the NIH for a comparative effectiveness trial, will enlist the collaboration of more than 150 medical centers around the U.S. and hundreds of sites in 33 countries worldwide. The ISCHEMIA trial enriches the population of patients enrolled by requiring documented proof of ischemia using non-invasive methods prior to enrollment and FFR as appropriate during the procedure.

"PCI outcomes have improved in the years since COURAGE, with second generation DES now standard of care and dramatic increases in the use of FFR and IVUS," continued Burnett. "Volcano now has close to 5,000 multi-modality FFR & Imaging capable systems installed around the world, and the use of FFR has more than tripled in the past three years. We are excited to support the ISCHEMIA trial by contributing our precision guided therapy tools like FFR and IVUS, and to better understand which therapy is right for each patient, especially when practicing modern day Functional PCI." About Volcano Corporation Volcano Corporation is revolutionizing the medical device industry with a broad suite of technologies that make imaging and therapy simpler, more informative and less invasive. Our products empower physicians around the world with a new generation of analytical tools that deliver more meaningful information - using sound and light as the guiding elements. Founded in cardiovascular care and expanding into other specialties, Volcano is changing the assumption about what is possible in improving patient outcomes by combining imaging and therapy together. ISCHEMIA is the only clinical trial mentioned in this press release supported by Volcano.

Forward-Looking Statements This press release contains forward-looking statements

within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this release that are not historical facts may be considered "forward-looking statements," including statements regarding the potential benefits of the products and procedures described above, further development and expansion, regulatory approval, commercial release and market adoption of the company's technology, and the impact of clinical and other technical data. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties which may cause Volcano's results to differ materially and adversely from the statements contained herein. Some of the potential risks and uncertainties that could cause actual results to differ include the pace and extent of market adoption of the company's products and technologies; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; unexpected manufacturing issues; growth strategies; timing and achievement of product development milestones; outcome of ongoing litigation; the impact and benefits of market development; product introductions; unexpected new data, safety and technical issues; market conditions; and other risks inherent to medical device development and commercialization. These and additional risks and uncertainties are more fully described in Volcano's filings made with the Securities and Exchange Commission, including our recent quarterly report on Form 10-Q. Undue reliance should not be placed on forward-looking statements which speak only as of the date they are made. Volcano undertakes no obligation to update any forward-looking statements to reflect new information, events or circumstances after the date they are made, or to reflect the occurrence of unanticipated events.

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