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## **Volcano's Proprietary iFR® Functionality Demonstrates Excellent Results in Presentations at EuroPCR 2012**

### **Evidence continues to build for functional lesion assessment with new tools that make measurements and guidance faster, easier**

SAN DIEGO, Calif., May 21, 2012 /PRNewswire/ -- Volcano Corporation (NASDAQ: VOLC), a worldwide leader in precision guided therapy tools, today provided an overview of data from multiple ground-breaking clinical trials presented last week at the EuroPCR conference, a key international cardiology meeting held in Paris, France.

"We provide tools that allow physicians to guide procedures based on functional data, in contrast to imprecise tools such as angiogram which provide images that are not always definitive," said Joe Burnett, Executive Vice President and General Manager of Volcano's Functional Measurement business unit. "Physiology, and particularly Fractional Flow Reserve (FFR), has been proven to improve outcomes in powerful, well-validated clinical trials like DEFER, FAME and now FAME II, which was presented this week at EuroPCR. As a pioneer in the field, we feel very strongly that there is tremendous potential for worldwide adoption of functional assessment across many clinical indications and FFR can be made faster, simpler and more cost effective — driving more personalized care and ultimately, better outcomes for patients."

### **Volcano's Proprietary Instant Wave-Free Ratio™ (iFR®) Functionality: An Emerging Tool**

Three datasets were presented for the first time at EuroPCR that expand the clinical data supporting Volcano's proprietary Instant Wave-Free Ratio™ Functionality (iFR® Functionality). The goal of iFR® Functionality is to provide a functional, lesion-specific assessment in seconds, without injecting a vasodilator drug to induce stress on the heart. The iFR® Functionality and algorithm are being developed in a collaboration between Volcano and researchers at the Imperial College London. Volcano iFR® Functionality is under development and not approved for sale in any markets.

"Today's technology enables us to explore coronary pressure and flow waveforms in a way that furthers our basic understanding of how coronary artery disease works — including the relationship of the coronary blockage itself with the surrounding myocardium," said Justin Davies, MD, PhD, Imperial College London. "Although the vast majority of iFR® Functionality and FFR cases 'agree', it is fascinating to look at the few cases where there is disagreement and to explore the physiology behind these cases."

Presented by Dr. Davies, the Adenosine Vasodilator Independent Stenosis Evaluation (ADVISE) Registry compared Volcano's proprietary iFR® Functionality with Fractional Flow Reserve (FFR) technologies, the gold standard test for evaluating lesion severity. Data from an all-comer registry of 339 lesions confirmed that Volcano's proprietary iFR® Functionality demonstrated an excellent correlation with FFR.

The ADVISE Registry enrolled 339 lesions across four sites in the United Kingdom and Spain, with a real-world clinical distribution of lesion severity. When compared to the intrinsic variability of FFR for the same lesion distribution, iFR® Functionality showed 94% relative diagnostic accuracy versus FFR (81% concordance observed in the distribution as a fraction of the 85% expected concordance for this clinical distribution). Of the cases showing discordance between iFR® Functionality and FFR, 41% lay within 0.01 of the FFR cut-off point (0.80), and 81% were within the FFR grey zone of 0.75-0.80.

The ADVISE Hyperemic Stenosis Resistance (HSR) Study assessed 51 lesions, calculating Volcano iFR® Functionality, FFR, and a third independent metric of lesion severity, HSR. iFR® Functionality showed the same diagnostic accuracy versus HSR (92%) as FFR versus HSR (92%). iFR® Functionality showed an Area Under the Curve (AUC) of 0.93 versus HSR, which had no statistical difference from the AUC of FFR versus HSR of 0.96 (p=0.48). The study also showed that in the 4 of 51 lesions (8%) that disagreed between Volcano iFR® Functionality and FFR, there was equal agreement with HSR. The data confirms that Volcano iFR® has comparable accuracy as FFR when both are compared to an independently validated metric of lesion severity (HSR).

An independently-conducted study presented by Dr. Jin Joo Park of Seoul National University Hospital enrolled 243 consecutive patients across 3 trial sites in Korea. Baseline pressure tracings (from which Volcano iFR® Functionality values could be derived off-line), along with FFR values using both intravenous and intracoronary adenosine, were obtained. The

baseline pressure tracings were sent to a Volcano iFR® Functionality core lab at Imperial College London in blinded fashion, meaning that the core lab operators were completely blinded to the corresponding FFR values. Of 238 lesions meeting pre-specified inclusion/exclusion criteria, the Area Under the Curve was 0.89 with diagnostic accuracy of 81%. On adjustment for the intrinsic variability of FFR for this distribution, relative diagnostic accuracy was 94%. This data demonstrates for the first time an excellent correlation of Volcano iFR® Functionality and FFR in a completely blinded analysis.

"Volcano iFR® Functionality has created an unprecedented interest among interventional cardiologists," commented Javier Escaned, MD, PhD from Hospital Clinico San Carlos in Madrid, Spain. "Since the online publication of the ADVISE study last December, over 800 patients have been analyzed to compare Volcano iFR® Functionality and FFR, and a very vivid debate on iFR® Functionality has taken place in scientific journals and international meetings. The European and South Korean registries presented in Paris, based on data analyzed with the ADVISE algorithms, reported a high diagnostic accuracy of Volcano iFR® Functionality in identifying FFR significant stenoses. This supports the concept that a robust analysis of data is crucial to calculate iFR® Functionality, and probably explains why the VERIFY registry, that uses a different analysis algorithm and was first presented at the ACC Congress last March, failed in reproducing ADVISE results."

"While we are extremely pleased with the performance to date, Volcano is committed to further clinical and mechanistic studies of iFR® Functionality, across multiple patient populations," added Neil Hattangadi, MD, Vice President and Business Unit Leader for Intravascular Therapies at Volcano. "We will launch global trials and perform analysis by a blinded, independent, iFR® Functionality core lab to ensure this metric continues to be rigorously validated."

### **New Developments in FFR**

Additionally, results from the FAME II (Fractional Flow Reserve-Guided Percutaneous Coronary Intervention Plus Optimal Medical Treatment vs. Optimal Medical Treatment Alone in Patients with Stable Coronary Artery Disease) study demonstrated clearly that patients with significant lesions identified via FFR did significantly better when stented compared with those treated with optimal medical therapy alone. This study was halted early by the independent Data and Safety Monitoring Board (DSMB) because the non-stenting (medically-treated) arm had significantly more urgent revascularizations than the FFR-guided stenting group. Data presented at EuroPCR 2012 showed an 11.2 times greater risk of urgent revascularization in the non-stenting group compared to the group that used FFR-Guided 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. Its 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.

### **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, growth strategies, timing and achievement of product development milestones, outcome of ongoing litigation, the impact of market development, decisions by regulatory bodies, 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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