



## **Volcano Corporation Announces Pioneering Vulnerable Plaque Study**

### **IVUS Imaging and Technology to Characterize Coronary Plaque Composition is Viewed as Central to Research Targeted at Vulnerable Plaque**

Rancho Cordova, CA - October 17, 2005 - Volcano Corporation today announced plans to conduct with Goodman Company and Fukuda Denshi a pioneering natural history of atherosclerosis study designed to increase clinical understanding of "vulnerable" plaques - lipid-rich necrotic coronary lesions that suddenly rupture - that may cause most heart attacks and plaque progression. The study will include 2,000 acute coronary syndrome patients receiving stents in Japan.

The study, called the SPECIAL (Study of Prospective Events in Coronary Intermediate Atherosclerotic Lesions) trial is in collaboration with Goodman, Fukuda Denshi, Toyohashi Heart Center, and up to 100 hospitals in Japan. SPECIAL will utilize novel IVUS (Intravascular Ultrasound) and IVUS-based plaque composition technology intravascular (VH™ IVUS) imaging technology from Volcano to collect data about characteristics of lesions not causing symptoms at the time of treatment. Additionally, for the first time ever in a large scale natural history of atherosclerosis trial, 1,000 patients will have IVUS and VH IVUS imaging 12 months post their initial intervention and examination. The study will correlate lesion characteristics, patient risk factors and other measurements with subsequent heart attacks and other cardiac events as well as plaque progression and regression, potentially paving the way for physicians to identify and treat at-risk patients before a heart attack occurs or plaque progresses to cause debilitating chest pain.

In the SPECIAL trial, Volcano's conventional IVUS technology and groundbreaking IVUS-based plaque composition technology (VH IVUS) will be utilized to collect data from the coronary arteries. IVUS is a catheter-based technology that provides clinicians with a high-resolution view of the coronary arteries from the inside. In an IVUS procedure, the IVUS catheter is connected to a console. The physician directs the catheter through the femoral artery, over the guide wire to the desired coronary artery. A microscopic transducer mounted on the tip of the catheter emits an ultrasound signal. The IVUS console processes the ultrasound signal as it bounces off the vessel wall, and an image of inside of the vessel is displayed. With conventional IVUS these images are in grayscale, but with Volcano's new IVUS-based plaque composition technology (VH IVUS) the plaque images can now be displayed in color, with plaque components shown as fibrous, fibro-fatty, dense calcium or necrotic core.

Principal Investigators for the study are Etsuo Tsuchikane, MD, PhD and Tadanori Aizawa, MD. Physician advisors include Tetsu Yamaguchi, MD, Satoshi Saito, MD, Osamu Katoh, MD, Takahiko Sukuki, MD, Gregg Stone, MD, Kenya Nasu, MD, and Pauliina Margolis, MD, PhD. Dr. Tsuchikane, from Toyohashi Heart Center and Columbia University College of Physicians and Surgeons commented, "While angioplasty and stents are remarkably effective in relieving chest pain in patients with known heart disease, there is currently no way to preemptively diagnose and treat the more than one million people every year having heart attacks or dying from unsuspected blockages in the arteries in the heart." Dr. Aizawa added, "The landmark SPECIAL trial is a major step to identify those patients with such "vulnerable plaques" at great future risk, in whom prophylactic therapy may prevent heart damage and save lives." Dr. Tsuchikane will outline the study's design in a presentation at Cardiovascular Research Foundation's (CRF) Seventeenth Annual Scientific Symposium, Transcatheter Cardiovascular Therapeutics (TCT 2005), in Washington, D.C. at 9 AM on October 19th.

"The SPECIAL study will collect critical new information about the role of vulnerable plaque in unexpected heart attacks and about the natural progression of coronary artery disease," said Pauliina Margolis, M.D. PhD, Medical Director for Volcano and study collaborator. "As a growing body of scientific knowledge about vulnerable plaque is built, physicians may one day be able to better predict and prevent heart attacks and plaque progression."

The cause of most heart attacks was once believed to be the gradual closing of arteries over time as plaque build-up slowly increased restricting blood and oxygen flow to the heart. However, the vast majority of heart attacks are now believed to be triggered by the rupture of a lipid-rich necrotic plaque hidden under the surface of the artery wall, causing blood to clot on the plaque and suddenly block the artery.

For this reason, heart attacks often occur in apparently healthy people who were unaware they have this type of plaque buildup in the walls of their arteries. Treadmill "stress tests," given to help determine whether blood supply is reduced in the arteries that supply the heart, do not indicate whether vulnerable plaque is present. Vulnerable plaques are not readily evident in angiograms either, as the hidden plaque may not yet block the vessel.

Scott Huennekens, President and CEO of Volcano Corporation added, "Volcano is extremely excited to work with Goodman, Fukuda Denshi and the clinical investigators on this groundbreaking trial. We anticipate the SPECIAL will collect valuable clinical information about the role of vulnerable plaques in heart attacks and the potential of Volcano's IVUS-based technologies to preemptively diagnose patients at risk -- so heart attacks can be prevented. This study continues Volcano's unparalleled commitment to research in the area of vulnerable plaque which also includes the ongoing PROSPECT trial in collaboration with Guidant and soon to begin IBIS-2 trial in collaboration with Glaxo Smith Kline."

### **About Volcano Corporation**

Volcano Corporation (formerly Volcano Therapeutics, Inc.) is a privately held medical device company founded in 2001. Investors and shareholders include Domain Associates, Johnson and Johnson Development Corporation, Medtronic, Ferrer, Freeman & Co. and OrbiMed Advisors.

With over 475 worldwide employees, Volcano is dedicated to providing technologies leading to optimal management of coronary artery and peripheral vascular disease. Volcano products include Intravascular Ultrasound (IVUS) systems and catheters, as well as physiology guide wires. With global distribution, Volcano is a leading provider of innovative therapy-enabling and therapy-guiding technologies to the interventional cardiology and peripheral vascular fields. For more information, please visit [www.volcanocorp.com](http://www.volcanocorp.com).

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