



Clinical Affairs Update Q 3, 2008

The following is a document summarizing Volcano's clinical study activities on a global basis. Our clinical study activity falls in three primary categories:

- 1) Drug eluting stent trials
- 2) Pharmaceutical plaque progression and regression studies
- 3) Vulnerable plaque in the coronary and peripheral artery studies

DRUG ELUTING STENT (DES) TRIALS

Stent Thrombosis

Volcano announced a collaboration whereby Volcano has agreed to provide intravascular ultrasound (IVUS) catheters free of charge for use in pivotal Drug Eluting Stent (DES) clinical trials. This offer will be made available to stent manufacturers utilizing the core lab services of Stanford, Cardialysis or CRF in trials where IVUS images and data are planned to be collected in 100% of patients at enrollment and at pre-determined follow-up periods.

The goal of the collaboration is to provide the stent industry, physicians and patients a more in-depth understanding of the complex phenomenon of stent thrombosis and the most definitive, expeditious answers to questions surrounding the long-term safety of current and next generation DES. In particular, IVUS is designed to precisely visualize late stent malapposition (when the coronary vessel grows away from the implanted stent months or years after deployment), which is emerging as a leading suspect in the search for the cause of late stent thrombosis in DES.

ADAPT-DES (Assessment of Dual AntiPlatelet Therapy with Drug-Eluting Stents)

Volcano is excited to participate in the ADAPT-DES trial being conducted in approximately 15 sites in both the US and Europe. ADAPT -DES is a prospective registry of at least 11,000 and up to 15,000 patients with coronary artery disease undergoing stent assisted intervention using DES. The objective of the study is to determine the frequency, timing and correlates (clinical and angiographic) of drug eluting stent thrombosis in the study population and the relationship of aspirin and/or clopidogrel response in this population.

There is an IVUS sub study that will include 3,000 patients to determine whether one or more IVUS parameters are independent predictors of stent thrombosis.

VULNERABLE PLAQUE TRIALS

Volcano is currently sponsoring or has co sponsored multiple trials investigating atherosclerosis risk stratification and vulnerable plaques in the coronary and peripheral arteries.

The studies range in design from Registries to Investigational Device Exemptions (IDE). Patient populations vary and include high risk patients as well as those suffering from metabolic diseases. The studies cover a broad array of varying designs and patient populations.

PROSPECT (Providing Regional Observations to Study Predictors of Events in the Coronary Tree) is one of the largest natural history studies with the objective to determine the likelihood of specific plaques and probabilities of rupture causing heart attacks. The endpoints included the use of Volcano's gray-scale IVUS and VH IVUS. It was conducted in approximately 40 US and European centers and enrolled 700 patients. The results of PROSPECT are expected to be shared at TCT in October 2008. Corporate sponsors of the PROSPECT Trial include Advanced Cardiovascular Systems, Inc., subsidiary of Abbott Vascular, Inc., and Volcano.

SPECIAL (Study of Prospective Events in Coronary Intermediate Atherosclerotic Lesions), is the study designed and organized by Japanese cardiologists and up to 100 hospitals in Japan are participating this study. SPECIAL will utilize novel IVUS (Intravascular Ultrasound) and IVUS-based plaque composition technology (VH IVUS) imaging technology from Volcano and will collect data focusing on characteristics of lesions not causing symptoms at the time of the treatment. Additionally, in a large scale natural history of atherosclerosis trial, 1,000 patients will have IVUS and VH IVUS imaging 12 months after 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 cardiac events. The study has recently closed to enrollment and the follow up is in process.

Volcano VH Registry is a registry that was conducted in over 40 sites in the US, Japan and Europe. Over 2500 patients were enrolled at these centers. The primary objective was to correlate plaque characteristics with patient demographics, clinical presentations and cardiac risk factors. Volcano's grayscale and VH IVUS technology was used in all cases. Enrollment into this registry was complete in April 2007. Data analysis and manuscript preparation is ongoing.

BLAST (Bifurcation Lesion Analysis and Stenting) Volcano is excited to sponsor the upcoming BLAST trial where we will demonstrate that IVUS with VH guidance leads to better post procedural outcomes when compared to angiography alone. 220 patients in approximately 15 sites in the US and Europe will be enrolled and randomized to using angiography or angiography with grayscale IVUS and VH to best determine the treatment of the lesion. Enrollment will start in Q3 of 2008.

PHARMACEUTICAL TRIALS

Volcano's IVUS and VH IVUS technologies have been an integral part of several pharmaceutical trials. Until now, conventional grayscale IVUS technology was the only type of IVUS used in such trials and the data collected was limited to plaque geometry.

TRUTH / KCPR is being conducted in Japan and the main objective is to enroll 160 patients into 2 arms. Patients will receive either pitavastatin or pravastatin to investigate regression of coronary arteriosclerosis, lipid levels, and inflammatory markers in patients with coronary heart disease. We will then evaluate plaque compositional change of the coronary artery with VH-IVUS; The evaluation lesion is defined as the lesion having more than 40% of plaque except 10mm distal and proximal of the lesion. PCI conducted. Secondary objectives include evaluation of the plaque compositional volume change of the coronary artery with VH-IVUS; MACE; Percentage and volume change of Serum lipid and other markers. The TRUTH study is closed to enrollment and the follow up is underway.

Tanabe drug study is also being conducted in Japan and will enroll a total of 60 patients, with half of those patients receiving Fluvastatin 30mg. The primary end point will be the reduction of NC volume at main vessels except treated vessels by Fluvastatin 6 month after PCI.

IBIS2 (in cooperation with GSK) Integrated Biomarker and Imaging Study 2 European multi-center, randomized, placebo-controlled one year treatment study in 330 ACS and non-ACS subjects with angiographically documented CAD. The objective of this study was to estimate the effect of GSK's Lp-PLA(2) inhibitor on circulatory biomarkers, endothelial dysfunction, coronary plaque volume and composition using grayscale IVUS, VH-IVUS and palpography. The results of this exciting trial were released at the ESC in Munich on September 1, 2008. The study showed that necrotic core continues to expand despite treatment with standard of care among patients receiving placebo. The publication can be found in *Circulation*. (2008;118:1172-1182.)

In Summary

Volcano IVUS technologies (grayscale and VH IVUS) have been used successfully and will continue to be used in global interventional trials. A review of the current bibliography of published data may be provided to you by your local sales or clinical representatives, or by going to the Volcano website at www.volcanocorp.com/clinical/clinical-papers-references.asp or to clinicaltrials.gov.

Volcano Corporation

2870 Kilgore Road
Rancho Cordova, CA 95670 USA
Phone: 800-228-4728
Field Service Direct: 916-861-0230
Fax: 916-638-8812
E-mail: info@volcanocorp.com

Volcano Clinical Affairs

7100 Euclid Ave #125
Cleveland, Ohio 44103
Phone: 216-426-6104

Volcano Europe

Excelsiorlaan 41
B - 1930 Zaventem
Belgium
Phone: + 32 2 679 10 76
Fax: + 32 2 679 10 72

Volcano Japan

Shinagawa Intercity Front 7F,
2-14-14, Konan
Minato-ku, Tokyo 108-0075