



CARDIOVASCULAR NEWS

World's smallest ICD successfully implanted in Canada!

OVATIO™, the world's smallest implantable cardioverter defibrillator (ICD), has been successfully implanted in Canada.

Smaller than a pager, OVATIO devices are the world's smallest ICDs. The physiologically shaped, long-lasting devices are capable of detecting and painlessly treating a wide range of arrhythmias (100 bpm - 255 bpm), thereby decreasing the risk for unnecessary shocks.

"[OVATIO is user-friendly, and very intuitive]. New features like AAIsafeR mode are definitely a plus," says Dr. Franck Molin, Professor, Electrophysiology Laboratory, Quebec Heart Institute, Laval University, Quebec City,

Quebec, who implanted the first OVATIO in Canada.

"The introduction of the OVATIO family reflects Sorin Group's drive to develop cutting-edge tachyarrhythmia management systems that are capable of respecting the heart's natural rhythm and bringing significant patient benefits," says Andre-Michel Ballester, President of Sorin Group Cardiac Rhythm Management (CRM) Business Unit.

OVATIO™, World's smallest implantable cardioverter defibrillator successfully implanted in Canada: New technology limits ventricular pacing. Press Release. Toronto, Canada, February 20, 2006.

Once again, Lipitor® safety is confirmed

Results of a recent retrospective analysis of 49 Lipitor® clinical trials, involving more than 14,000 patients, showed that the overall rates of treatment-related adverse events reported by patients taking the highest dose of Lipitor® were low and similar to those reported by patients who received placebo or the lowest dose of Lipitor®. The analysis is published in the current edition of the American Journal of Cardiology.

Dr. Gregg Larson, Pfizer vice president of US Cardiovascular Medical, has said that this evidence is timely because it allows physicians to meet the demands of aggressively lowering their patients' cholesterol safely with higher doses of Lipitor®.

The analysis, which included Lipitor® clinical trials that were initiated and completed between 1992 and 2004, tracked the incidence of non-serious and serious muscle, liver and kidney adverse events and laboratory tests. The analysis compared 7,258 patients who received Lipitor®,

10 mg, to 4,798 patients taking Lipitor®, 80 mg, and 2,180 patients taking placebo. The average age of men and women in the analysis was 59 (the oldest patients were over 90 years). Patients had varying degrees of cardiovascular risk.

Lipitor® was well-tolerated, with the most adverse events related to the digestive system. The incidence of myalgia was low and similar in patients taking Lipitor®, 10 mg and 80 mg doses. Myopathy was rare and unlikely related to the dosage. There were no reported cases of rhabdomyolysis. Elevated liver enzymes were more frequently observed in patients taking 80 mg doses, compared to 10 mg doses of Lipitor®.

Lipitor®'s safety again confirmed in extensive analysis of 49 clinical trials, Pfizer says. Important and timely information for physicians intensively treating their patients' cholesterol. Patients taking high dose (80 mg) Lipitor® reported adverse events similar to patients taking low dose or placebo. Press Release. Kirkland, Quebec, January 24, 2006.

ACTOS® reduces chance of further heart attack

New results from the PROactive Study found that ACTOS® (pioglitazone) significantly reduced the occurrence of fatal and non-fatal heart attacks by 28% and acute coronary syndrome (ACS) by 37% in high-risk patients with Type-2 diabetes who had a previous non-fatal heart attack. Importantly, these benefits were above and beyond those seen with standard care treatment.

ACTOS significantly reduced the combined risk of non-fatal heart attacks, strokes and death by 16% in patients with Type-2 diabetes and cardiovascular disease. There was a 19% risk reduction in the combined cardiac endpoint of cardiac death, non-fatal MI, coronary revascularisation and ACS.

The beneficial results of PROactive should not be generalised to any other oral anti-diabetic medication.

The PROactive Study was funded by Takeda Pharmaceutical Company Limited, the makers of pioglitazone (marketed under the trade name ACTOS®) and Eli Lilly and Company.

For more information, visit www.proactive-results.com

Takeda's ACTOS® (pioglitazone) reduces risk of further heart attack by 28% in patients with Type 2 diabetes: PROactive Study also shows a 37% reduction in acute coronary syndrome with ACTOS®. Press Release. London, UK, November 16, 2005.

Rimonabant maintains improvements for up to two years

Sanofi-aventis announced the results of the RIO-North America trial in *The Journal of the American Medical Association (JAMA)*.

The trial evaluated two-year treatment with rimonabant in overweight or obese patients, many of whom were at increased risk for diabetes and heart disease through the presence of additional risk factors. Findings showed that patients treated with rimonabant, 20 mg once daily, experienced significant reduction of their waist circumference and body weight, as well as improvements in multiple cardiometabolic risk factors, including HDL cholesterol, triglycerides and an estimate of insulin sensitivity.

At one year, the weight loss and reduction in waist circumference for all patients treated with rimonabant, 20 mg, once daily, enrolled in the study trial were significantly greater than placebo. Patients treated with rimon-

abant, 20 mg, once daily, for two years, achieved an average of 3.6 kg (7.9 lbs) greater weight loss than those in the placebo group. In contrast, those patients switched to placebo for the second year of treatment regained the majority of the weight they had lost the previous year.

The RIO-North America trial concluded that, rimonabant—the first CB₁ blocker—produced sustained, clinically meaningful weight loss and favourable changes in cardiometabolic risk factors, including HDL cholesterol, triglycerides and HOMA estimated insulin sensitivity.

Rimonabant was discovered by researchers at sanofi-aventis.

Journal of the American Medical Association publishes the RIO-North America Study: Study shows rimonabant maintains improvements in multiple cardiometabolic risk factors for up to two years. Press Release. Paris, France, February 14, 2006.

Tracleer® shown to be efficacious for the treatment of PAH in children

Pulmonary arterial hypertension (PAH) is a chronic, life-threatening disorder characterized by abnormally high BP in the arteries between the heart and lungs of an affected individual. Function of the heart and lungs is severely compromised, resulting in limited exercise capacity, and, ultimately, a reduced life expectancy.

A analysis published in the Journal of the American College of Cardiology (JACC), found that Tracleer®, the first oral dual endothelin receptor antagonist, was shown to be efficacious for the treatment of PAH in children. In addition, this study also indicated that the safety profile appears similar to that in adult PAH patients.

Approximately 11% of PAH patients receiving Tracleer® experienced abnormal but reversible liver enzyme elevations. It is therefore important that patients undergo monthly liver monitoring. Due to the risk of birth defects, women who are pregnant, or of childbearing age that do not use a reliable method of contraception, must not take Tracleer®.

Tracleer® has been made available worldwide by Actelion Ltd (SWX.ALTN), a biopharmaceutical company.

Journal of the American College of Cardiology (JACC) publication on Tracleer® in children with PAH: Retrospective Analysis highlights efficacy data on long-term use. Press Release. Allschwil, Switzerland, August 18, 2005.

ASCOT study shows reductions in mortality and strokes

A clinical study by the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT) provides new evidence for the optimal treatment of Canadians with high BP. This hypertension study involved approximately 20,000 patients in Europe, and was designed to determine whether newer hypertension treatment regimens are superior to older approaches. The study compared a calcium channel blocker (amlodipine besylate)-based treatment regimen with a standard beta-blocker-based treatment in reducing cardiovascular events in hypertensive patients with multiple cardiovascular risk factors.

Results show that patients taking a calcium channel blocker-based treatment regimen (amlodipine besy-

late) experienced significant reductions in cardiovascular mortality (24%), all-cause mortality (11%) and incidence of stroke (23%) along with coronary events, and were also less likely to develop diabetes.

Dr. Robert Petrella, President of Blood Pressure Canada claims “rarely do we see a person with just one risk factor for cardiovascular disease. It is much more common to see someone with high BP who has additional risk. As physicians, we need to look at the whole patient and the entire risk profile...and avoid treating the individual risk factors”. *PCad*

Landmark Hypertension Study shows Reductions in MORTALITY and STROKES. Press Release. London, Ontario, September 4, 2005..