Long-term safety of Tracleer® confirmed in PAH subgroups

Two abstracts presented at the European Society of Cardiology conference confirm the long-term safety profile of Tracleer® (bosentan) in treating pulmonary arterial hypertension (PAH). Data presented from 579 European patients with PAH associated with congenital heart disease (CHD) and 470 patients with chronic thromboembolic pulmonary hypertension (CTEPH) showed that potential safety signals were recorded in 19.7% and 34.5% of patients, respectively. This compares with 36.7% seen in patients with idiopathic PAH.

“These results show that in both CTEPH and CHD patients treated with bosentan, the safety profile of bosentan appeared similar with that seen in the original pivotal clinical PAH studies. This is reassuring for physicians who have patients with CTEPH and CHD requiring treatment,” commented Professor Joern Carlsen from the Department of Cardiology at the Rigshospitalet in Copenhagen.

CTEPH is a serious condition characterized by longstanding obstruction of the large pulmonary arteries, leading to the impairment of normal blood flow through the lungs. This induces hypoxaemia and pulmonary hypertension, eventually leading to respiratory insufficiency and right heart failure.


Preclinical studies show the angiotensin II receptor blocker (ARB) Micardis (temisartan) has a beneficial effect on metabolic parameters, including plasma glucose, insulin resistance and lipid abnormalities, in addition to its proven effect on high blood pressure (BP) due to its partial activation of peroxisome proliferator-activated receptor (PPAR)-gamma.

PPAR-gamma is a hormone receptor known to have an important role in regulating carbohydrate and lipid metabolism by increasing insulin sensitivity. High BP, lipid abnormalities, insulin resistance and obesity are key components of metabolic syndrome, a common precursor of cardiovascular disease and Type 2 diabetes.

The Micardis molecule is structurally similar to the PPAR-gamma activator pioglitazone, which has been approved for the treatment of Type 2 diabetes.

In the largest clinical study of its kind, UCLA researchers found that early treatment with a statin drug within 24 hours of having a heart attack reduced in-hospital mortality rates by more than 50 per cent. The new study, published in the September 1 issue of the American Journal of Cardiology, demonstrates that early statin therapy may be essential for reducing mortality and other complications in heart attack victims.

Researchers found that patients who received statin therapy before hospitalization and within 24 hours following a heart attack had a 54 per cent lower risk of in-hospital mortality compared to patients not on statin therapy. Patients who had not received previous statin therapy, but who were newly started on the medication within 24 hours of hospitalization, had a 58 per cent reduction in mortality compared to patients not on statin therapy.

“We’ve known that long-term statin therapy is beneficial, but this study provides the strongest clinical evidence to date supporting the early cardioprotective effects of statins immediately following a heart attack,” said Dr. Gregg C. Fonarow, lead study author.

Statin treatment within first 24 hours after heart attack cuts in-hospital mortality by more than half. Press Release. Los Angeles, August 29, 2005.

Novartis Pharmaceuticals Canada Inc. announced recently that Health Canada has approved Diovan (valsartan) for a new indication to reduce cardiovascular death in patients at high risk (with heart failure or left ventricular dysfunction) following a heart attack. Diovan is the world’s most prescribed angiotensin receptor blocker (ARB) for mild-to-moderate hypertension.

Currently, one in three patients who survives a heart attack will die within one year. “Medications like valsartan are an important tool in our therapeutic strategy to reduce morbidity and mortality in this patient group who often can’t or won’t take their medications due to side-effects,” said Dr. Kenneth R. Melvin, a Toronto cardiologist. “Valsartan is proven to be more tolerable than some of the first-line therapies used to treat heart attack survivors; so, while offering excellent blood pressure control, it supports better compliance.”

The number of deaths due to cardiovascular disease (CVD) is projected to grow seven times faster than Canada’s population by the time the baby boomers reach their seventies (2021-2031), according to demographer David Foot, author and Professor of Economics at the University of Toronto. Further, CVD hospitalizations will grow three times faster than the population over the next 45 years, a significant figure, given that not all cases of CVD involve hospitalization. Implications include new challenges for Canada’s health-care system, including increased demands on resources, both fiscal and human, and the need for individual risk-reduction strategies.

The report, “The Shape of Things to Come: A National Report on Heart Disease and the Challenges Ahead,” commissioned by Becel in support of World Heart Day (September 25, 2005), forecasts the impact of an aging population on future trends in CVD over the next 45 years (to 2051) and provincial trends for the next 20 years (to 2026). The three areas of focus include deaths due to CVD, hospitalizations due to CVD and obesity as a major risk factor for CVD. The report also includes practical recommendations on how Canadians might reduce their risk for CVD and adopt a healthy heart lifestyle.


Landmark data from the PROspective pioglitAzone Clinical Trial In macroVascular Events (PROactive), presented at the 41st annual meeting of the European Association for the Study of Diabetes, demonstrated that pioglitazone (ACTOS®) significantly reduces the risk of heart attacks, strokes and death in high-risk patients with Type 2 diabetes.

This result is a breakthrough for patients who are at high risk for heart attacks, strokes or premature death, as it is the first time that an oral diabetes medication has shown significant reductions in these cardiovascular (CV) events.

“The PROactive study found that pioglitazone has the potential to save lives and help delay or reduce the risk of CV events in people with Type 2 diabetes,” said Dr. Dormandy, Professor of Vascular Sciences at St. George’s Hospital, London, UK, and Chairman of the PROactive study steering committee. “The PROactive study is the first study in the world to show that a specific diabetes medication, namely pioglitazone, normally used to control blood glucose, can also significantly improve patient outcomes associated with CV disease in patients with Type 2 diabetes, which means people with Type 2 diabetes can potentially benefit from longer and healthier lives.”