Medical Briefs

An abridged look at current events in and around the health-care industry

This Month:

New Role for Cozaar®

Health Canada has approved Cozaar® (losartan potassium) to delay the progression of kidney disease in people with Type 2 diabetes, kidney disease, and high blood pressure. Cozaar continues to be indicated for the treatment of high blood pressure. The new indication for Cozaar is based on the results of the landmark RENAAL (Reduction of Endpoints in Non-insulin dependent diabetes mellitus with the Angiotensin II Antagonist Losartan) study, published in the *New England Journal of Medicine* in September 2001.

Implication: "With no proven treatments for delaying end-stage renal disease available on the market, we are very pleased to have Cozaar as a new tool to combat this debilitating and potentially fatal disease," said Dr. James Scholey, professor of medicine at the University of Toronto. "End-stage renal disease is costly, both in terms of quality of life and health-care dollars," he added. More than 1.3 million Canadians have been diagnosed with diabetes and among these, 800,000 are also affected by high blood pressure.

Health Canada Approves Cozaar® To Treat Diabetic Patients With Kidney Disease and High Blood Pressure. Press Release, Montreal, Quebec, May 7, 2003.

STARTing Asthma Treatment Early

The Lancet has recently published findings from the START (Steroid Treatment As Regular Therapy in early asthma) study. START is a five-year study involving more than 7,000 children and adults who suffer from mild persistent asthma. It is the first and largest international study to evaluate the benefits of early treatment with Pulmicort® (budesonide), an inhaled corticosteroid.

Implication: Key findings from the first three years of the study showed that in patients with recent onset, mild, persistent asthma, once-daily treatment with Pulmicort significantly reduced the risk of a first severe asthma-related event by 44%. Pulmicort was well tolerated and was not associated with any increase in non-asthma-related adverse events. Until the START study, there was a lack of long-term, real-life clinical data to support earlier use of inhaled steroids in mild persistent asthma. Globally, more than 180,000 people die from asthma every year, including 500 Canadians.

Asthma is a Serious Disease.Press Release, Montreal, Quebec, May 5, 2003.

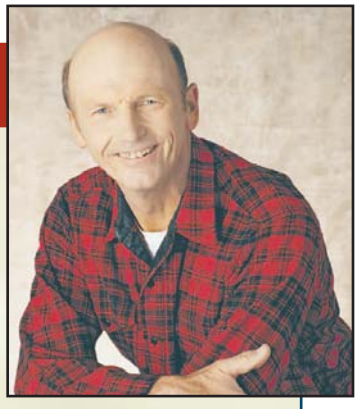
Zometa®: A Broad Range of Functions

Health Canada has recently approved the use of Zometa® (zoledronic acid) for the prevention of skeletal complications in patients with a broad range of advanced cancers which have spread to the bone. The approval is based on data from three large, international clinical trials evaluating more than 3,000 patients with prostate cancer, breast cancer, lung cancer, myeloma, and other solid tumour types. Zometa was previously only indicated in patients with advanced prostate cancer.

Implication: In clinical trials, Zometa was shown to decrease the skeletal complications of patients with bone metastasis from solid tumours and mutiple myeloma. It delayed the time to the first skeletal event, decreased the number of patients with skeletal-related events, and prevented potential bone complications. It is the only bisphosphonate to have demonstrated efficacy in such a broad range of tumour types.

Zometa, First and Only Bisphosphonate to Demonstrate Efficacy Across a Broad Range of Cancers. Press Release, Dorval, Quebec, April 30, 2003.

Satisfaction Guaranteed With Levitra™



New clinical findings on men's perceptions of their sexual experiences showed that men with erectile dysfunction who were taking 10 mg or 12 mg of Levitra™ (vardenafil HCI) reported significantly improved satisfaction with erection hardness, orgasmic function, and overall sexual experience. The most common side-effects were mild to moderate headache, flushing, and rhinitis.

Implication: "Ultimately, it's the quality of the erection that can lead to satisfying sexual experience," said Dr. Myron Murdock, national medical director of *www.hisandherhealth.com*. "These findings show that Levitra improves the quality of erection and improves a man's overall satisfaction with his sexual experience compared with placebo."

New Clinical Findings Show Satisfaction With Sexual Experience and Erection Quality Improved with Levitra™. Press Release, Chicago, Illinois, April 28, 2003.

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Altace®: Efficient and Cost-Effective for Heart Failure

Two new Canadian-led studies published in *Circulation* demonstrated that Altace® (ramipril) significantly reduced the onset of symptomatic and, often fatal, heart failure, and is a cost-effective treatment for patients at high risk of cardiovascular disease. An estimated 200,000 to 300,000 Canadians, most of whom are women, have heart failure. Researchers looked at data from 9,291 patients who completed the HOPE (Heart Outcomes Prevention Evaluation) study. Altace was shown to reduce the risk of heart failure by 23% compared to placebo. Patients who received Altace also had a lower rate of hospitalization and death due to heart failure.

Implication: "This trial extends the benefit of angiotensin-converting enzyme inhibitors beyond what was previously proven," said the study's lead author, Dr. Malcolm Arnold, a professor of medicine at the University of Western Ontario. "It shows for the first time that heart failure can be prevented in a broad range of high-risk patients."

New Analyses of Landmark HOPE Study Show Altace® Reduces Heart Failure and Demonstrated Cost-Effectiveness for Treatment of High-Risk Cardiovascular Patients. Press Release, Laval, Quebec, April 23, 2003.

A More Economical Epilepsy Treatment

New cost-effectiveness data presented in April at the American Academy of Neurology congress showed add-on therapy with Keppra® (levetiracetam) is a cost-effective alternative to standard treatment of refractory epilepsy. The incremental cost-effectiveness analysis showed substantial benefits if seizure freedom can be obtained by the addition of Keppra at a relatively modest cost.

Implication: This news has important implications for the treatment of epilepsy around the world, with potentially substantial benefits for patients, as well as health-care budgets. Epilepsy is the most common serious neurologic condition in the world, with estimates ranging between 40 and 50 million active sufferers. Epilepsy management incurs substantial direct and indirect costs on the health-care system, the patients, and their caregivers due to the chronic nature of the disease.

Economic Evaluation Shows Add-On Therapy With Keppra® is a Cost-Effective Alternative to Maintenance of Standard Therapy for the Treatment of Refractory Epilepsy. Press Release, Brussels, Belgium, April 3, 2003.

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Lipitor® Reducing Risk of Heart Attack and Stroke

The landmark ASCOT (Anglo-Scandinavian Cardiac Outcomes Trial) study has shown that patients with mildly elevated cholesterol levels, who took the cholesterol-lowering drug Lipitor® (atorvastatin calcium) had 36% fewer fatal coronary events and non-fatal heart attacks than patients treated with placebo. The study included 19,342 patients with high blood pressure.

Implication: "These reductions in cardiovascular events occurred earlier than we've seen in many other clinical studies," said Dr. Peter Sever, ASCOT co-chair. Dr. Sever also noted the results could impact how this particular patient population is treated, as patients with high blood pressure and only mildly elevated cholesterol levels are not routinely considered for cholesterol-lowering therapy.

Reduction in Heart Attacks and Strokes Shown in Hypertensive Patients Treated With Lipitor®. Press Release, Kirkland, Quebec, April 2, 2003.

New Hope for Breast Cancer Patients

A landmark Phase III clinical study, the CALGB9741 trial, supports the benefits of a shortened chemotherapy regimen to treat node-positive primary breast cancer following surgery that significantly improves survival and risk of cancer recurrence. The randomized study involved 1,973 women. Results showed significant benefits when Taxol® (paclitaxel) was given along with Cytoxan® (cyclophosphamide) and Adriamycin® (doxorubicin) every two weeks instead of every three weeks. This treatment method is called dose-dense therapy.

Implication: At three years, the relative risk reduction for cancer recurrence was 26%. At four years, disease-free survival was 82%. Since the data were presented in December 2002, this therapeutic approach is still being considered as treatment for early-stage breast cancer in North America. In Canada, one in nine women is expected to develop breast cancer during her lifetinme. One in 27 will die from it.

Innovative "AC-Taxol Dose-Dense" Treatment Significantly Reduces Cancer Recurrence and Mortality in Early Breast Cancer. Press Release, Toronto, Ontario, April 1, 2003.

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Double the Dosage of URSO™

Axcan Pharma Inc. recently launched URSO™ (ursodiol) in a 500 mg tablet dosage form (URSO DS) in Canada for the treatment of cholestatic liver diseases. This new dosage form compliments the 250 mg USRO tablets Axcan already makes in Canada for the treatment of this condition.

Implication: Mr. Léon F. Gosselin, Axcan's president and CEO, said the new dosage will allow patients to take fewer tablets per day on a lifetime basis; this new dosage should also improve compliance. The Canadian market for URSO is valued at approximately $5 million US annually. The company is currently investigating the use of other formulations of ursodiol to treat various other diseases, such as nitric oxide-releasing derivative of ursodiol in the treatment of portal hypertension, and ursodiol disulfate in the prevention of colorectal polyps recurrence.

URSO™ 500 mg Tablets Launched in Canada for the Treatment of Cholestatic Liver Diseases. Press Release, Mont Saint-Hilaire, Quebec, March 24, 2003.

Pumping Up!

Not all proton pump inhibitors (PPIs) have the same gastric acid suppressive effects at their recommended daily doses. When it comes to bioavailability, as much as 77% of the PPI Pantoloc® (pantoprazole sodium) is bioavailable after the first dose. In contrast, only 35% of Losec® (omeprazole) is bioavailable after the first dose. Of all the PPIs, pharmacologic data suggest the longest half-life of acid suppression was also identified in Pantoloc.

Implication: Dr. Alan Thomson, a University of Alberta professor and author of a paper on PPIs, said, "We continue to gain important insights regarding how to optimally treat patients with gastroesphogeal reflux disease and the PPI Pantoloc may offer advantages to some patients. The benefits for patients on Pantoloc include lower propensity for double dosing at its recommended dose of 40 mg and a reduction in physician visits. Ultimately, these actions may result in cost savings to the health-care system.

Treating Heartburn: Are All Medications Equal? Press Release, 2003.