

# Medical Briefs

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

## At a glance:

- Pneumonia
- Prostate Cancer
- Renal Failure
- Asthma
- Hypertension
- Cardiovascular Disease
- Herpes

## New Weapon for Warts

Stiefel Canada Inc., the leading dermatology company in Canada, announced an agreement with 3M Canada to supply their Nexcare™ brand protective cover-up bandages for Duofilm® Patch (with Comfort Spots) and Duoplant® (with Comfort Strips) to provide more convenience and protection.

This agreement emphasizes the continued commitments of Stiefel to supply the highest quality of protection with the Duofilm family of products. Packages have been redesigned to enhance the overall identity of the brand.

For years, physicians and pharmacists have recommended the Duofilm family of products to patients as a safe and effective line of wart removal products.

*We're Giving Effective Wart Therapy a Whole New Look.* Press Release, Montreal, Quebec, November 1, 2002.



## Good News for Prostate Cancer Patients

For 75 per cent of advanced prostate cancer patients the complications of bone metastases is a constant and painful reminder of their struggle with this disease. With the approval of Zometa® (zoledronic acid for injection), patients with bone metastases due to prostate cancer have access for the first time, to a treatment that can ease their pain and restore their quality of life.

Granted priority review by Health Canada, Zometa has been approved for the treatment of complications from bone metastases due to prostate cancer in conjunction with standard antineoplastic therapy including chemotherapy and hormonal therapies. Priority review is granted to those drugs which are shown to fill significant unmet medical needs. Before the approval of Zometa, there was no effective treatment that specifically targeted the bone metastases resulting from prostate cancer.

“Advanced prostate cancer commonly spreads to the bone and causes a variety of complications that can significantly impact a patient’s day-to-day activities,” Dr. Fred Saad said. He is urologist-oncologist at the Centre hospitalier de l’Université de Montréal, Notre-Dame site. “Zometa represents a significant advance in the overall treatment of advanced prostate cancer patients and is a welcome therapeutic addition.”

*Health Canada Approves Drug that Addresses Unmet Need for Prostate Cancer Patients.* Press Release, Dorval, Quebec, October 9, 2002.

## Preventing Renal Failure: The Right CCB

New evidence suggests that reducing the risk of progressive renal failure may significantly depend on what class of blood pressure medication is prescribed, according to a recent review article in the *New England Journal of Medicine*.

While the general consensus for treating diabetics with nephropathy and hypertension has been to initiate antihypertensive therapy with agents like angiotensin converting enzyme (ACE) inhibitors, optimal control of blood pressure and proteinuria, the addition of agents, such as calcium channel blockers (CCBs), may be necessary.

According to the review article, authored by Dr. Giuseppe Remuzzi, nephrologist from the Mario Negri Institute of Pharmacological Research in Bergamo, Italy, not all CCBs have produced positive results among diabetics at risk for kidney failure. CCBs can be divided into two classes: dihydropyridine (DHP) and non-dihydropyridine (non-DHP).

According to Dr. Remuzzi, renal benefits for the patient population may only exist when treatment consists of a non-DHP CCB, such as verapamil and diltiazem. "Clinical evidence points to the fact that non-DHP CCBs, such as verapamil and diltiazem, actually reduce proteinuria and slow the progression of nephropathy in diabetics."

Tiazec<sup>®</sup> (diltiazem HCl) is a once daily non-DHP calcium channel blocker that effectively reduces blood pressure of hypertensive patients over a 24-hour dosing interval, with a side-effect profile comparable to placebo, even when dosed up to 360 mg.

*150% Increase in Kidney Disease in the Past 10 years.* Press Release, Toronto, Ontario, October 1, 2002.

## Valtrex<sup>®</sup> Reduces Herpes Transmission

Once-daily suppressive therapy with Valtrex<sup>®</sup> (valacyclovir hydrochloride) caplets reduced transmission of symptomatic genital herpes by 77 per cent versus the placebo group, according to data presented at the 42nd annual meeting of the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC).

Valtrex is the only product that has been studied for the reduction of the transmission of genital herpes in heterosexual monogamous couples and is currently indicated by Health Canada for the suppression of genital herpes outbreaks.

"Suppression with valacyclovir 500 mg once-daily provides a brand new tool in herpes transmission prevention," said Dr. Sacks, infectious diseases physician and professor of pharmacology and therapeutics at the University of British Columbia. "People with genital herpes will want to have an honest herpes discussion with their sexual partner, consider type-specific blood testing for the partner to determine if he or she is susceptible, and use, as we recommend in the study, safer sex as the third principle in prevention. Suppressive therapy adds a novel tool which is very effective."

*Landmark Study Shows Suppressive Antiviral Therapy with Valtrex<sup>®</sup> Caplets Reduced Sexual Transmission of Genital Herpes.* Press Release, Mississauga, Ontario, September 30, 2002.

# Medical Briefs

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## Help in the Fight Against Heart Attacks

Initial results from a major clinical trial involving Pfizer Inc.'s cholesterol lowering medicine Lipitor® (atorvastatin calcium) showed that Lipitor provided a significant benefit in reducing a fatal and non-fatal heart attacks as well as strokes.

The study, known as the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT) involving nearly 20,000 patients with high blood pressure, was designed to compare the effects of newer anti-hypertensive medicines with standard therapies in reducing cardiac events. In addition, half of the patients enrolled received either a 10 mg dose of Lipitor or placebo to measure the effects of lowering cholesterol in patients who had high blood pressure and cholesterol levels that were normal or slightly elevated.

As a result of significant benefit demonstrated by Lipitor, the independent ASCOT steering committee has decided to stop the Lipitor portion of the study. All patients in the study will be notified and instructed to contact their physician for appropriate followup. Final results of the Lipitor portion of the study will be made public when available.

*Pfizer's Lipitor Showed Significant Benefit in Reducing Heart Attacks and Stroke.* Press Release, New York, New York, October 10, 2002.

## Alternative for Heart Failure Patients

Data published in the *Journal of the American College of Cardiology* demonstrates that valsartan, Diovan® an angiotensin 2 receptor blocker (ARB), significantly reduced heart failure mortality by 33 percent, morbidity by 44 per cent and hospitalisations by 56.4 per cent. This was compared with placebo in patients from the Valsartan Heart Failure Trial (Val-HeFT) who also took standard heart failure therapies, but not angiotensin converting enzyme (ACE) inhibitors.

Based on the findings of Val-HeFT, Diovan recently became the only ARB approved in the U.S. for the treatment of heart failure in patients who cannot tolerate ACE inhibitors. Despite their known benefits, studies have shown that 20 per cent to 54 per cent of heart failure patients are not prescribed ACE inhibitors because of side effects or other factors. Treatment guidelines by the European Society of Cardiology (ESC) and other organizations already recommend the use of ARBs, such as Diovan, for patients who cannot tolerate ACE inhibitors.

“While ACE inhibitors are known to reduce mortality and morbidity from heart failure, many patients are not prescribed these drugs because concerns about side effects,” said author professor Aldo Maggioni, a Val-HeFT investigator from Italy's Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto. “Our analysis suggests that valsartan can serve as a safe, effective substitute for ACE inhibitors for the management of heart failure.”

*Diovan (Valsartan) Improved Survival and Reduced Hospitalizations in Heart Failure Patients Who did not Take ACE Inhibitors.* Press Release, Basel, Switzerland, October 16, 2002.

## GlaxoSmithKline Shows its Green Thumb

GlaxoSmithKline (GSK) announced the availability of a new environmentally-friendly delivery system for its inhaled asthma formulations Flovent® (fluticasone propionate) and Ventolin® (salbutamol sulphate) in Canada.

New Flovent HFA and Ventolin HFA metered dose inhalers (MDIs) deliver these well-tolerated and effective asthma medications via a chlorofluorocarbon-free (CFC-free) propellant. GSK developed the CFC-free propellant for its MDIs in compliance with the terms of the Montreal Protocol, an international agreement endorsed by more than 170 countries to regulate the use and production of CFCs. While pharmaceutical usage of CFCs as a propellant in MDIs and other inhalation aerosols is minute, the transition of CFC-free MDIs will help to further protect the environment.

“While GSK strives to produce medications that safely and effectively treat medical conditions, we’re also committed to protecting the environment,” Dr. Anne Philips said. She is vice-president, research and development and chief medical officer for GSK. The company has invested more than \$400 million to develop CFC-free alternatives for Flovent and Ventolin.

*Flovent HFA and Ventolin HFA Inhalers Employ Environmentally-Friendly Delivery System.* Press Release, Mississauga, Ontario, October 21, 2002.

## Cholesterol-Lowering Drug Approved

Following a 10-month study, Merck/Schering-Plough Pharmaceuticals announced the FDA has approved Zetia™ (ezetimibe), the first in a new class of cholesterol-lowering agents that inhibits the intestinal absorption of cholesterol. The once-daily tablet of Zetia 10 mg was approved for use either by itself or together with statins in patients with high cholesterol to reduce LDL “bad” cholesterol and total cholesterol. Cholesterol-lowering medicines should be used in addition to an appropriate diet when the response to diet and exercise has been inadequate. In clinical trials, Zetia was generally well tolerated with an overall side effect profile similar to placebo.

Sixty per cent of the estimated 13 million patients taking statins continue to have LDL cholesterol higher than recommended levels,” Dr. H. Bryan Brewer said, chief of molecular disease branch, National Heart, Lung and Blood Institute, National Institutes of Health (NIH). “As the first breakthrough to treat cholesterol since statins were introduced 15 years ago, Zetia provides physicians with a new option to get more of these patients to goal. This is particularly important in view of last year’s changes to the NIH’s cholesterol guidelines, which substantially expand the number of Americans eligible for drug therapy and call for lower cholesterol goals for many people,” Dr. Brewer said.

*FDA Approves Zetia (Ezetimibe) for Cholesterol Reduction.* Press Release, Whitehouse Station, New Jersey, October 25, 2002.

# Medical Briefs

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## HOPE for Women With Cardiovascular Disease

A study, representing one of the largest ever of women and cardiovascular disease (CVD), published in the *Journal of the American College of Cardiology*, concludes that women who are at high risk of developing CVD and are treated with the widely prescribed ACE inhibitor Altace® (ramipiril) receive the same cardio-protective benefits as men. The study, a pre-planned sub-study of the landmark Heart Outcomes Prevention Evaluation (HOPE) study, recommends that high-risk, post-menopausal women should consistently be treated with ACE inhibitors.

“Until now, women, in general, have been under-represented in clinical trials of cardiovascular disease,” said Dr. Eva Lonn, associate professor of medicine and cardiology, McMaster University and member of the international steering committee of the HOPE trial. As CVD is the leading cause of death among women in industrialized countries, it’s absolutely critical to identify preventive strategies for women, especially now, when heart disease and its risk factors (increasing life expectancy, diabetes and hypertension) are on the rise among women.”


*Women in Landmark Canadian Cardiovascular Study Fare as Well as Men.* Press Release, Laval, Quebec, October 30, 2002.

## Beating Resistant Pneumonia

Canadian data from one of the largest ongoing surveillance studies on antibiotic resistance show that telithromycin (Ketek™) is effective in fighting *Streptococcus pneumoniae* that are resistant to even the most commonly prescribed classes of antibiotics.

Results from the Prospective Resistant Organism Tracking and Epidemiology of the Ketolide Telithromycin (PROTEKT) study were presented at the 42nd annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in San Diego, California. Approximately 90 centres in 26 countries, including eight centres in six Canadian provinces, have been collecting data on the most common pathogens responsible for respiratory tract infections, including *Streptococcus pneumoniae*.

Of the 350 *Streptococcus pneumoniae* isolates collected in Canada, 17 per cent were resistant to macrolides and quinolones, the two most commonly prescribed antibiotics for respiratory tract infections. Telithromycin was active in 100 per cent of isolates resistant to macrolides and quinolones.

“With ever growing concerns about resistance, our objective is to use antibiotics as little as we can. With such an efficacy profile, telithromycin could quickly become an agent of choice over macrolides and quinolones,” Dr. Jacques la Forgea said. He is pneumonologist at the Institut de cardiologie et de pneumologie de l’Hôpital Laval in Sainte-Foy, Quebec and professor at Université Laval. 

*Canadian Data Demonstrate Effectiveness of New Antibiotic In Bacteria Resistant to Commonly Prescribed Agents.* Press Release, Laval, Quebec, September 30, 2002.