

# Medical Briefs

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

## New Weapon to Battle Pneumonia

Studies presented at the 42nd annual Interscience Conference on Antimicrobial Agents and Chemotherapy confirm the efficacy of Ketek® (telithromycin) in the treatment of community-acquired pneumonia caused by *Streptococcus pneumoniae*. Ketek, taken once-daily, was compared to clarithromycin, administered twice-daily, for periods of five to 10 days. Clarithromycin is one of the most commonly prescribed antibiotics in Canada.

The analysis of two phase-three clinical trials also determined that Ketek is effective against bacteria resistant to erythromycin.

Data collected from the two multicentre, randomized, double-blind trials compared Ketek to clarithromycin in the treatment of community-acquired pneumonia among 1,023 patients. Patients were treated with either Ketek, 800 mg once-daily for periods varying from five to 10 days, or clarithromycin, 500 mg twice-daily for five to 10 days. Results showed Ketek was clinically and bacteriologically active in 97.1% of patients while clarithromycin was effective in 90.2% of patients. Ketek was also shown to be active in 88.9% of patients presenting erythromycin-resistant *Streptococcus pneumoniae* compared to 75% of resistant patients treated with clarithromycin.

*First in a New Class of Antibiotics.* Press Release, Laval, Quebec, September 27, 2002.

## New Therapy in Treating Hepatitis C

The combination of Pegasys®, a new generation pegylated interferon for treatment of hepatitis C, with ribavirin provides a considerable clinical advantage over combining interferon alfa-2b and ribavirin, reports a new study published by the *New England Journal of Medicine*. Interferon alfa-2b plus ribavirin has been the leading prescribed hepatitis C therapy in Canada since its introduction.

“This study showed that Pegasys combination therapy has significantly improved efficacy compared to our current standard of treatment. What is really gratifying is that this comes with an improved tolerance. The side effects that are often most troubling, namely flu-like symptoms and depression, occurred less frequently with Pegasys combination therapy than standard therapy. This means fewer patients will have to stop therapy because of side effects,” Dr. Morris Sherman said, a hepatologist at the Toronto General Hospital.

*New England Journal of Medicine Reports That Pegasys® Combination Provides “Considerable Clinical Advantage” Over Current Therapy.* Press Release, Mississauga, Ontario, September 26, 2002.

## Good News for Baby Boomers' Sex Lives

About three million Canadian men are faced with the physical and emotional lows associated with erectile dysfunction (ED). It is clear that both the incidence and severity of ED increases with age. This is of major significance, given Canada's exploding baby boomer population.

Fortunately, there are treatment options for men who suffer from ED. A new medication, apomorphine, targets the dopamine receptor in the brain, said to be the first step in the erectile process.

Apomorphine is a dopamine receptor agonist that works in the brain to improve diminished erectile function by enhancing the natural signal to the penis following sexual stimulation, similar to the way men normally have erections. Apomorphine works through the central nervous system, producing a series of events that enhances the ability to achieve and maintain penile erection.

"Apomorphine is distinct from other oral therapies, which act by blocking the action of certain enzymes involved in the erectile response. Furthermore, apomorphine is administered sublingually, entering the bloodstream quickly and bypassing the gastrointestinal tract. The rapid absorption into the bloodstream allows for its fast onset action, typically under 20 minutes," Dr. Peter Pommerville explained, a urologist at the Royal Jubilee Hospital in Victoria, BC.

*Erectile Difficulties: A Problem on the Rise.* Press Release, Montreal, Quebec, September 25, 2002.

## Hope for Erectile Dysfunction

Findings from two clinical trials investigating the efficacy of Levitra™ (vardenafil HCl) will be presented at the 10th World Congress of the International Society for Sexual and Impotence Research in Montreal. In Canada, the Therapeutic Products Directorate of Health Canada is presently reviewing Levitra for efficacy and safety, but market authorization has not yet been obtained.

In the first study, men with erectile dysfunction (ED) who were taking the investigational oral drug Levitra reported consistently improved erectile function the first time they took the drug and subsequently thereafter. For the three months of the study, involving more than 800 ED patients, Levitra was reported to consistently improve rates of successful penetration, intercourse success and overall satisfaction during first and subsequent attempts.

In another study, the first of its kind to assess the effect of phosphodiesterase (PDE-5) inhibitor on erectile function and depressive symptoms among men with ED resulting from prostate cancer surgery, results showed that men taking Levitra were more likely to report improved erections and fewer depressive symptoms than men taking the placebo.

*Canadian-Led International Studies Show Men Treated with Levitra Report Reliable Improvement in Erectile Function Over Time and Improvements in Erection Quality Following Prostate Cancer Surgery.* Press Release, Montreal, Quebec, September 23, 2002.

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## More Effective Treatment for Bipolar Disorder

AstraZeneca announced data from the first in a series of phase three trials with Seroquel® (quetiapine). The data show that combining Seroquel with a mood stabilizer is significantly more effective than mood stabilizers alone for the treatment of bipolar mania. The data, presented at the third European Stanley Foundation Conference on Bipolar Disorder in Freiburg, Germany, also show that initiation of Seroquel treatment is simple and well tolerated.

“The results show not only that Seroquel is effective in treating acute mania, but also that more patients treated with Seroquel experienced a full resolution of their manic symptoms compared to patients taking mood stabilizers alone,” Dr. Gary Sachs said, lead investigator from the Harvard Medical School in Boston.

The study is part of a comprehensive bipolar disorder clinical trial program to examine the efficacy of quetiapine adjunctive and monotherapy to treat bipolar mania. Analysis of further clinical trials will be completed later this year.

*First Phase 3 Data Confirm Seroquel in Combination With Mood Stabilizer is Significantly More Effective Than Mood Stabilizers Alone in Treating Bipolar Mania.* Press release, Alderley Park, United Kingdom, September 13, 2002

## One Quarter of the Obese Population is Diabetic

Over one quarter of obese people may have previously undetected or untreated Type 2 diabetes or pre-diabetes (impaired glucose tolerance), according to data presented at the European Association for the Study of Diabetes (EASD) meeting in Budapest, Hungary. This data translates to 100 million people worldwide who may be at risk for the serious health problems associated with untreated diabetes.

The data presented at EASD were new findings from the Xenical® in the prevention of Diabetes in Obese Subjects (XENDOS) study. The results of the one-year landmark XENDOS study, involving 3,301 patients, demonstrated that the weight loss medication Xenical can prevent or delay the development of Type 2 diabetes. The XENDOS study data also showed significant and sustained weight loss with Xenical over the long term.

Excess weight is well recognized as the most important modifiable risk factor for the development of Type 2 diabetes. Type 2 diabetes often goes undetected and untreated for many years. During this period, diabetic complications, such as heart disease, nerve damage and stroke can develop.

*Type 2 Diabetes and Pre-Diabetes are Undetected in Over One Quarter of Obese Population.* Press Release, Basel, Switzerland, September 3, 2002.

## Birth Control Patch Approved in Canada

A new prescription birth control method for Canadian women, the first contraceptive patch, has been approved by Health Canada. Known as Evra<sup>®</sup>, this patch is applied once a week, and provides the same protection as the birth control pill against unintended pregnancy.

Evra is a smooth, beige square and is thin enough to be worn discreetly underneath clothing and delivers continuous levels of progestin and estrogen, the same active ingredients in the pill.

Similar to birth control pills, Evra stops the ovaries from releasing an egg for fertilization and makes it difficult for sperm to enter the uterus by thickening the mucus in the cervix. Evra is worn for one week at a time and is replaced on the same day of the week for three consecutive weeks. The fourth week is “patch-free.” Women can wear Evra discreetly on the buttocks, upper torso (front or back, excluding the breasts) or upper outer arm.

In clinical trials, Evra was well tolerated. Some side effects (which are similar to oral contraceptives) women experienced include breast tenderness, headache, application site reaction, nausea, upper respiratory infection, menstrual cramps and abdominal pain.

*Once a Week Birth Control Option — The Patch — Approved in Canada.* Press Release, Toronto, Ontario, August 22, 2002.

## McGill Receives \$1,000,000 for Osteoporosis Research

Novartis Pharmaceuticals Canada Inc. has contributed \$1,000,000 to Canada’s largest osteoporosis study, which is being directed by researchers from the Research Institute of the McGill University Health Centre. This funding will help support the second phase of research of the Canadian Multicentre Osteoporosis Study (CAMOS) which will focus on ways to prevent and eliminate osteoporotic fractures in the elderly.

“Osteoporosis is a debilitating bone disease that effects approximately 25% of individuals over 50 years of age,” Dr. Allen Tenenhouse said, director of the division of bone metabolism, department of Medicine, McGill University Health Centre. “The objective of CAMOS is to free Canadian seniors from the threat of osteoporosis and fractures. Through collaborations, such as the one with Novartis, I am hopeful that we can achieve this objective.”

Phase one of the CAMOS began in 1995, and a second five-year phase began in January 2002. The study involves over 9,000 participants and takes place in nine centres across Canada, from St. John’s to Vancouver. The study will provide better insight into the prevention and causes of osteoporosis.

*McGill University Health Centre Receives \$1,000,000 From Novartis Pharmaceuticals.* Press release, Montreal, Quebec, August 21, 2002.