

FOR IMMEDIATE RELEASE

First New Opioid Dependence Treatment in More Than 30 years

^NSUBOXONETM approved by Health Canada and available as new, effective and safe treatment option for patients with opioid drug dependence

Kirkland, Quebec – December 11, 2007 – Schering-Plough Canada Inc. announced today that for the first time in more than 30 years, Canadians who are dependent on opioids, such as heroin and opioid-based prescription pain medications including hydromorphone and oxycodone, have a new, effective and safe treatment option to combat their disease. ^NSUBOXONETM (buprenorphine / naloxone) was recently approved by Health Canada, and is now available for substitution treatment in opioid drug dependence in adults. SUBOXONE, a tablet that dissolves under the tongue, suppresses the symptoms of opioid withdrawal and reduces the cravings for opioid drugs.ⁱ

“Most of the approximately 125,000 illicit drug users in Canada are opioid dependentⁱⁱ, and three-quarters of these people are not in treatment for their disease.ⁱⁱⁱ We now have a new treatment option that will help our patients manage their symptoms.” said Dr. François Couturier, Family Physician and associate professor at l’Unité de médecine familiale of the Charles-Lemoyne Hospital, in Longueuil and affiliated to l’Université de Sherbrooke. “Additionally, from a safety perspective, when treating with SUBOXONE, there is lower potential for intravenous misuse.”

Designed for recovery and safety

Guy-Pierre Lévesque, General Manager at the Méta d’Âme Support Center in Montréal Quebec, describes SUBOXONE as a new intervention that will bring much needed choice to patients who rely on medical treatment as part of their recovery plan.

“When patients first enter treatment, our main goal is to stabilize them physically and socially, enabling them to remain in treatment,” said Mr. Lévesque. “With SUBOXONE now available for opioid dependent patients in Canada, this new treatment option can help them start taking control of their disease and help them get on – and stay on – the road to recovery.”

SUBOXONE combines buprenorphine with naloxone.^{iv} Buprenorphine, a partial opioid agonist, helps to manage the cravings associated with opioid withdrawal.ⁱ The naloxone component of SUBOXONE reduces the potential for misuse^{iv} by causing unpleasant withdrawal symptoms if the product is misused by intravenous injection.^v

Treatment may include take-home doses after a period of two months, based upon an assessment of the patient's clinical stability, and their ability to safely store the product at home.

"The availability of SUBOXONE in Canada is a part of a long-awaited solution to our need for a new treatment option for our patients," said Dr. Marsh, Physician Leader of Addiction Medicine with Vancouver Coastal Health and Providence Health Care, Clinical Associate Professor at the University of British Columbia, and Past-President of the Canadian Society of Addiction Medicine. "It's important to have a new choice, and arming physicians with another weapon to fight opioid dependence will only serve to help patients manage this disease."

To help ensure appropriate use of SUBOXONE, Schering-Plough Canada is also offering an online education program, accredited by The College of Family Physicians of Canada, for healthcare professionals. The program provides professionals with information needed for product use, supports the dialogue between patient and physician about the risk and benefits of therapy and encourages an approach to care involving the careful monitoring of patients within a framework of medical, social and psychological support as part of a comprehensive opioid dependence treatment program.^{iv} Schering-Plough is dedicated to improving patient access to treatment for this disease. SUBOXONE should only be prescribed by physicians who have experience in the substitution treatment in opioid drug dependence, and have completed the accredited SUBOXONE Education Program. Physicians can obtain more information about the SUBOXONE Education Program by calling 1-800-463-5442 or visiting www.SUBOXONECME.ca.

Opioid dependence in Canada

Only one-quarter (25 per cent) of Canadians who are dependent on opioid drugs, are in treatment.ⁱⁱⁱ Illegal drug use represents an estimated annual cost to society of more than \$8.2 billion (in terms of burden on services such as health care and law enforcement, the loss of productivity in the workplace or at home resulting from disability and premature death).^{vi} Over the last decade, a change in illicit drug use has been noted with more drug users abusing prescription opioid drugs, such as hydromorphone and oxycodone.^{vii} These prescription opioid drugs come either directly or indirectly from the medical system, rather than from illicit production and distribution.^{viii}

About SUBOXONE

Approved by Health Canada in May, 2007^{ix}, SUBOXONE is indicated for substitution treatment of opioid drug dependence in adults. The intention of the naloxone component is to deter intravenous misuse. Patients prescribed SUBOXONE should be carefully monitored within a framework of medical, social and psychological support as part of a comprehensive opioid dependence treatment program.^{iv} The approval is based on results of a four-week safety/efficacy study in 326 subjects

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with a maximum daily dose of 16 mg and a 48-week open-label safety study involving 461 patients.^x SUBOXONE is taken once a day as a sublingual tablet placed under the tongue to dissolve.^{iv}

Prescribing practices

SUBOXONE sublingual tablets should only be prescribed by physicians who have experience in substitution treatment in opioid drug dependence and have completed an accredited SUBOXONE Education Program. SUBOXONE is a narcotic and appropriate security measures should be taken to safeguard stocks of SUBOXONE against diversion. Abuse and diversion of buprenorphine have been reported. Physicians should not prescribe SUBOXONE sublingual tablets unless the condition of daily intake supervised by a healthcare professional can be ensured, except for week-ends and holidays, for a minimum of two months and until the patient is clinically stable and able to safely store SUBOXONE take home doses.^{iv}

Adverse events

The most common treatment-related adverse events reported during clinical trials with SUBOXONE were those related to withdrawal symptoms (e.g., abdominal pain, diarrhea, muscle aches, anxiety, sweating).^{iv}

Additional safety information

The safety and efficacy of SUBOXONE have not been established in patients under 18 years of age and over 65 years of age. SUBOXONE should not be administered to women who are pregnant or who are breast-feeding or to patients who have severe respiratory insufficiency, severe hepatic insufficiency, acute alcoholism, or delirium tremens. SUBOXONE should not be taken together with alcoholic drinks or medications containing alcohol. Alcohol increases the sedative effect of buprenorphine. SUBOXONE should be used cautiously together with benzodiazepines as this combination may result in death due to respiratory depression of central origin, therefore, dosage reduction of one or both medications must be considered. Unless the benzodiazepines are prescribed by a physician, this combination should be avoided due to the risk of misuse. Patients should be warned of the potential danger of the self-administration of other Central Nervous System depressants. SUBOXONE can produce drug dependence of the opiate type.^{iv}

About Schering-Plough

Schering-Plough Canada Inc. is a country operation of Schering-Plough Corporation that employs over 950 people across Canada. Schering-Plough Canada Inc.'s web site is www.schering-plough.ca.

Schering-Plough is an innovation-driven, science-centered global health care company. Through its own biopharmaceutical research and collaborations with partners, Schering-Plough creates therapies that help save and improve lives around the world. The company applies its research-

and-development platform to human prescription and consumer products as well as to animal health products. In November 2007, Schering-Plough acquired Organon BioSciences, with its Organon human health and Intervet animal health businesses, marking a pivotal step in the company's ongoing transformation. Schering-Plough's vision is to "Earn Trust, Every Day" with the doctors, patients, customers and other stakeholders served by its approximately 50,000 people around the world. The company is based in Kenilworth, N.J., U.S.A. and its Web site is www.schering-plough.com.

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FOR MORE INFORMATION

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B-roll footage is also available for download via satellite at the following coordinates:

DATE OF FEED:	Tuesday, December, 11, 2007
TIME OF FEED:	2:00 PM ET – 2:30 PM ET
CO-ORDINATES:	Anik F2 C, Transponder 7B
	Audio subcarrier 6.2 and 6.8
	Downlink frequency 3980 vertical
TOC	CFA TX 1

Alternatively, you can access the footage via CNW's on-demand service at the following link:
http://cnw.pondeserver.com/story_details.asp?fn=163.

ⁱ Buprenorphine Sublingual and Buprenorphine and Naloxone Sublingual. Medline Plus Web site. Available at: www.nlm.nih.gov/medlineplus/druginfo/medmaster/a605002.html. Accessed Oct. 3, 2007.

ⁱⁱ Fischer B, Cruz MF, Rehm J. Illicit Opioid Use and Its Key Characteristics: A Select Overview and Evidence from a Canadian Multi-site Cohort of Illicit Opioid Users (OPICAN). *Can J Psychiatry* 2006;51(10):624-634.

ⁱⁱⁱ Fischer B, Chin AT, Kuo I, et al. Canadian illicit opiate users' views on methadone and other opiate prescription treatment: an exploratory qualitative study. *Subst Use Misuse* 2002;37:495-522.

^{iv} SUBOXONE (buprenorphine / naloxone) Product Monograph, Schering-Plough Canada Inc.; May 2007.

^v Subutex and Suboxone Approved to Treat Opiate Dependence. U.S. Food and Drug Administration Web site. Available at: www.fda.gov/bbs/topics/ANSWERS/2002/ANS01165.html. Accessed July 27, 2007.

^{vi} Rehm J, Baliunas D, Brochu S, et al. *The Costs of Substance Abuse in Canada 2002*. Ottawa, ON: Canadian Centre on Substance Abuse; 2006:1. Available at: www.ccsa.ca/NR/rdonlyres/18F3415E-2CAC-4D21-86E2-CEE549EC47A9/0/ccsa0113322006.pdf. Accessed August 30, 2007.

^{vii} Haydon E, Rehm J, Fischer B, et al. Prescription drug abuse in Canada and the diversion of prescription drugs into the illicit drug market (Commentary). *Can J Public Health* 2005;96(6):459-61

^{viii} Fischer B, Rehm J, Patra J, et al. Changes in illicit opioid use across Canada. *CMAJ* 2006;175(11):1385-1387.

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ix Notice of Compliance Information. Health Canada Web site. Available at: www.nocdatabase.ca/. Accessed July 6, 2007.

^x Fudala PJ, Bridge TP, Herbert S, et al. Office-based treatment of opiate addiction with a sublingual-tablet formulation of buprenorphine and naloxone. *N Engl J Med* 2003;349:949-958.