

Pfizer Japan to Launch Champix(R) the First Prescription Oral Smoking Cessation Aid in Japan

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hibits A Sense Of Satisfaction Associated With Smoking And Relieves Tobacco Craving

([BUSINESS WIRE](#))--Pfizer Inc announced today that on May 8, 2008, it will launch Champix® Tablet 0.5mg/1mg (varenicline tartrate), a novel smoking cessation aid for smokers with nicotine dependence in Japan, which has one of the highest rates of smoking among developed nations.

Champix was developed as the first non-nicotine drug designed for smoking cessation in the United States and will be the first oral smoking cessation aid available in Japan. The currently available smoking cessation aids such as 'Nicotine Replacement Therapy' (NRT) relieve withdrawal symptoms associated with smoking cessation by replacing tobacco use through delivering nicotine. In contrast, Champix brings about a smoking cessation effect through a new mechanism of action which works by selectively targeting the $\alpha 4\beta 2$ nicotine receptors in the brain to reduce both craving and withdrawal symptoms and reduce the pleasure associated with smoking.

Champix reduces withdrawal symptoms and tobacco craving associated with smoking cessation by acting on the same receptor in the brain as nicotine (the $\alpha 4\beta 2$ nicotine receptor) but with higher affinity. Champix partially stimulates the receptor and triggers a reduced dopamine response, which helps to relieve the craving and withdrawal symptoms associated with stopping smoking. At the same time, Champix prevents nicotine from binding at the receptor, so if a smoker slips and smokes a cigarette, Champix reduces the reward and sense of pleasure associated with smoking.

"Pfizer is delighted to be able to provide patients and physicians in Japan with Champix, a breakthrough medicine for smoking cessation that has helped millions of smokers who want to quit," said Jeff Kindler, chairman and chief executive officer of Pfizer. "Furthermore, we are gratified that health authorities in Japan recognize the benefits of therapies such as Champix that address a major unmet medical need."

Champix's approval in Japan was based on a 12-week, randomized, double-blind, placebo-controlled study in Japanese smokers who wanted to quit smoking. The primary endpoint, the percentage of subjects who did not smoke at all during the four consecutive weeks between Week 9 and Week 12 was 65.4 percent (85/130 cases) in the Champix 1mg twice-daily group and 39.5 percent (51/129 cases) in the placebo group, a statistically significant difference between the two groups. The most common side effects of Champix were nausea, headache, and constipation, but most of them were mild.

As of April 1, 2006, medical service providers under the Japanese national health insurance (NHI) system which meet certain registration criteria are designated as 'smoking cessation treatment facilities' and can fully reimburse the cost of smoking cessation treatments to patients with nicotine dependence. In order for a patient to receive NHI treatment, he or she must meet certain requirements.

“Smoking is a chronic, relapsing medical condition and one of the leading causes of preventable disease, death and disability in the world,” said Hiromitsu Iwasaki, president and chief executive officer of Pfizer Japan. “Champix represents a major clinical advance for smoking cessation which we hope, together with counseling, will help patients end their addiction to the nicotine in tobacco.”

With the launch of Champix, Pfizer Japan will introduce a website for patients with nicotine dependence called “SUGU KIN-EN (Smoking Cessation Now) at www.sugu-kinen.jp” as of May 8, 2008. This website provides easy-to-understand guidance on smoking cessation and treatment options. The website also offers a list of medical institutions that provide smoking cessation treatment throughout Japan.

Japan has one of the highest rates of smoking among developed nations, with approximately 26 million smokers. Although many smokers want to quit, studies show that withdrawing from nicotine dependence using willpower alone is very difficult because smoking is a chronic relapsing medical condition that typically involves a physical and psychological addiction to nicotine. In light of this information, the NHI approved coverage for smoking cessation treatments in April 2006, thereby enabling patients to receive treatment for nicotine addiction by physicians. Approved in more than 60 countries, Champix has been used by more than 5 million people around the world. The launch of Champix in Japan will bring another medical option for smoking cessation treatment, and it will contribute to more effective smoking cessation treatment for patients with nicotine dependence.

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