

Pfizer Japan Receives Manufacturing and Marketing Authorization for Champix(R)

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The First Oral Smoking Cessation Aid in Japan

([BUSINESS WIRE](#))--Pfizer Japan Inc (headquarter in Shibuya-ku, Tokyo; headed by President & Chief Executive Officer, Hiromitsu Iwasaki; and capitalized at Yen 64.8 billion) announced that on January 25, the company received manufacturing and marketing authorization for Champix® Tablet 0.5 mg/1mg (varenicline tartrate), a smoking cessation aid for smokers dependent on nicotine.

Champix is Japan's first oral smoking cessation aid developed for smoking cessation treatment. Current 'Nicotine Replacement Therapy' relieves withdrawal symptoms associated with smoking cessation by replacing tobacco with nicotine. Champix brings about a smoking cessation effect as a non-nicotine partial agonist¹ that binds to $\alpha_4\beta_2$ nicotine receptors in the brain with strong affinity.

Champix relieves withdrawal symptoms and tobacco craving associated with smoking cessation by acting as an agonist for $\alpha_4\beta_2$ nicotine receptors in the brain, which are associated with nicotine dependence. At the same time, if a person smokes a cigarette while receiving treatment, Champix acts as an antagonist to inhibit nicotine from binding to $\alpha_4\beta_2$ nicotine receptors, restricting the patient's sense of satisfaction associated with smoking.

In a 12-week, randomized, double-blind, placebo-controlled study in Japanese smokers who wanted to quit smoking, the primary endpoint (the 4 consecutive-week smoking cessation rate between Week 9 and Week 12) was 65.4 percent (85/130 cases) in patients receiving 1mg Champix twice-daily and 39.5 percent in the placebo group (51/129 cases) respectively, showing a statistically significant difference between the two groups.

Many smokers are suffering from nicotine dependence. At the same time, many smokers who desire and attempt to quit smoking end up without cessation.² Nicotine dependence is a chronic disease that is difficult to overcome solely with a smoker's willpower. To successfully quit smoking, a combination of medical support and medication is effective. Pfizer Japan believes that by introducing Champix, we will be able to help many nicotine dependent smokers quit smoking successfully, thus creating a healthier environment in Japan.

Champix was launched under the product name of Chantix® in August 2006 in the United States and of Champix® in December 2006 in European Union. At present, the product is approved in more than 60 countries around the world, and used for smokers who want to quit smoking. In Japan, it was filed for approval by the Ministry of Health, Labor and Welfare (MHLW) in June 2006 and it was approved on January 25, 2008.

Note:

1. A partial agonist is a substance that, while functioning as an agonist solely, works as an antagonist when another agonist exists. (In case of Champix, nicotine contained in tobacco acts as another agonist.)

2. Source: 'Survey on Nicotine Dependency and Realities in Smoking Cessation Behavior' (2006) by Osaka Medical Center for Health Science and Promotion

Outline of Champix®

Product name: Champix® Tablet 0.5 mg/1mg

Generic name: Varenicline tartrate

Date of manufacturing authorization: January 25, 2008

Production and distribution by: Pfizer Japan Inc.

Effect-efficacy: Smoking cessation aid for smokers with nicotine dependence

Dosage and administration: Normally, for an adult, 0.5 mg as varenicline should orally be administered once daily after a meal from Day 1 to Day 3. From Day 4 to Day 7, 0.5 mg should orally be administered twice daily after breakfast and dinner. On Day 8 and after, 1 mg should orally be administered twice daily after breakfast and dinner. Champix should be administered for a period of 12 weeks.

Features:

- It is Japan's first non-nicotine oral smoking cessation aid based on a new action mechanism.
- It shows high smoking cessation rates in smokers with nicotine dependence.
- It restricts a sense of satisfaction obtained with smoking.
- It relieves withdrawal symptoms and tobacco craving associated with smoking cessation.

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