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FDA Approves Novel Medication for Smoking Cessation

The U.S. Food and Drug Administration (FDA) announced today the approval of Chantix (varenicline tartrate) tablets, to help cigarette smokers stop smoking. The active ingredient in Chantix, varenicline tartrate, is a new molecular entity that received a priority FDA review because of its significant potential benefit to public health.

Chantix acts at sites in the brain affected by nicotine and may help those who wish to give up smoking in two ways: by providing some nicotine effects to ease the withdrawal symptoms and by blocking the effects of nicotine from cigarettes if they resume smoking.

"Tobacco use, particularly cigarette smoking, is the single most preventable cause of death in the United States and is responsible for a growing list of cancers as well as chronic diseases including those of the lung and heart," said Scott Gottlieb, MD, Deputy Commissioner for Medical and Scientific Affairs. "The agency is committed to helping facilitate the development of products to help people quit smoking and improve their overall quality of life."

According to the Centers for Disease Control and Prevention (CDC), an estimated 44.5 million adults in the United States smoke cigarettes and more than 8.6 million of them have at least one serious illness caused by smoking.

"Cigarette smoking is a very difficult habit to break due in large part to nicotine dependence or addiction" said Dr. Steven Galson, Director of FDA's Center for Drug Evaluation and Research. "Chantix therapy has proven to be effective in smokers motivated to quit and will provide another tool for physicians to use for the millions of smokers who want to quit."

The effectiveness of Chantix in smoking cessation was demonstrated in six clinical trials, which included a total of 3659 chronic cigarette smokers who were treated with varenicline. Five of the six studies were randomized, controlled clinical trials in which Chantix was shown to be superior to placebo in helping people quit smoking. These smokers had previously averaged 21 cigarettes a day for approximately 25 years. In two of the five placebo-controlled studies, Chantix-treated patients were also more successful in giving up smoking than patients treated with Zyban (bupropion).

The approved course of Chantix treatment is 12 weeks. Patients who successfully quit smoking during Chantix treatment may continue with an additional 12 weeks of Chantix treatment to further increase the likelihood of long-term smoking cessation.

In clinical trials, the most common adverse effects of Chantix were nausea, headache, vomiting, flatulence (gas), insomnia, abnormal dreams, and dysgeusia (change in taste perception).

Chantix is manufactured and distributed by Pfizer, Inc., New York, NY.