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HEADLINE: New Aid to Smoking Cessation Treatment Available to Help Smokers Declare Independence from Cigarettes; Zyban(TM) (bupropion hydrochloride) Sustained-Release Tablets Now Available by Prescription

DATELINE: RESEARCH TRIANGLE PARK, N.C., July 1

BODY:

A new prescription medicine to help people quit smoking and declare their independence from cigarettes is making its way to drug stores in time for the Fourth of July. Zyban(TM) (bupropion hydrochloride) Sustained-Release Tablets offer smokers the first nicotine-free prescription medicine and an entirely new way to help people quit.

Zyban, cleared for marketing by the U.S. Food and Drug Administration on May 14, is indicated as an aid to smoking cessation treatment. Accompanying Zyban at no additional cost is a personalized patient support program called the Zyban Advantage Plan(TM).

"There is no better time than the present to declare your independence from nicotine," says Michael C. Fiore, MD, director of the Center of Tobacco Research and Intervention at the University of Wisconsin Medical School. "Zyban is an important advance that will help many people break this powerful addiction to cigarettes. It is important that smokers who want to quit, seek medical attention and determine the best treatment plan to put them on the road to improved health."

Zyban is a tablet and is nicotine-free which is distinctly different from nicotine replacement therapy. Zyban is thought to work on the biology of nicotine addiction -- specifically in the brain. While it is not clear how Zyban works, it is presumed to affect the noradrenergic and/or dopaminergic systems in the brain which have been implicated as pathways of nicotine addiction.

The effectiveness of Zyban as an aid to smoking cessation was demonstrated in two placebo-controlled, double-blind studies. Over 1,500 chronic smokers who smoked at least 15 cigarettes a day participated. In one study, Zyban was compared to placebo; in the second study, Zyban was evaluated versus placebo, a nicotine patch (Habitrol(R)), and in combination with the patch. In both studies, all patients received brief individual smoking cessation counseling.

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In the study involving the patch, patients treated with Zyban had significantly higher 4-week quit rates than those treated with the patch. Patients treated with the combination of Zyban and the patch had significantly higher quit rates than those treated with the patch alone. Quit rates with combination therapy, while higher, were not statistically significantly higher than quit rates with Zyban alone. The 4-week quit rates from this second study were 23% for placebo; 36% for the patch; 49% for Zyban and 58% for Zyban and the patch.

Results from the two studies demonstrated that patients treated with Zyban 300 mg/day had more than a two-fold chance of quitting than patients treated with placebo. Quit rates in clinical trials are affected by the population selected and may be lower for the general population.

For many patients, treatment with Zyban reduced withdrawal symptoms. Withdrawal symptoms showing the most pronounced reductions were: irritability, frustration or anger, anxiety, difficulty concentrating, restlessness, and depressed mood or negative affect. In patients treated with Zyban, there was also evidence of a reduction in craving for cigarettes or urge to smoke.

The most common side effects associated with the use of Zyban were dry mouth and insomnia. These side effects are mild and often disappear in a few weeks. The use of Zyban is also associated with a dose-dependent risk of seizure. Therefore, higher than recommended doses should not be used and Zyban should not be used in people who are taking other medications containing bupropion (i.e. Wellbutrin(R), or Wellbutrin SR(R)). Zyban also should not be used in patients with a seizure disorder or who have a history or are currently diagnosed with bulimia or anorexia nervosa. It also should not be used in people who are taking a monoamine oxidase inhibitor (MAOI). It is important that patients tell their healthcare professionals about all medicines -- prescription and over-the-counter -- they are taking or plan to take.

"Zyban offers smokers a new approach to smoking cessation," says Andrew Johnston, PharmD head of Psychiatry Clinical Research at Glaxo Wellcome, "and when combined with the Zyban Advantage Plan provides smokers with timely, tailored information and specific smoking cessation techniques to help improve the chances of individual success."

When samples of Zyban are dispensed in the healthcare provider's office or when the initial prescription of Zyban is filled at the pharmacy, the smoker also receives the Zyban Advantage Plan which includes a medication booklet, program guide, patient questionnaire and a quit preparation workbook. In addition, each smoker who enrolls in the Zyban Advantage Plan by calling 1-800-UCAN-QUIT (800-822-6784) or by mailing in the patient questionnaire from the kit receives a customized plan to help them quit smoking. Zyban and the Zyban Advantage Plan are part of a comprehensive smoking cessation treatment as recommended by a healthcare professional.

In addition to the Zyban Advantage Pack, Zyban is also available in a refill bottle of 60 tablets. The recommended dose of Zyban as an aid to smoking cessation treatment is one 150 mg. tablet taken once daily for three days, followed by one 150 mg. tablet taken twice daily for 7-12 weeks. Patients start

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Zyban before they quit smoking and are advised to set a date to stop smoking during the second week of therapy to allow Zyban to reach adequate blood levels. The medicine is priced competitively to nicotine replacement therapy and costs approximately \$2.56 per day of treatment. Zyban is currently priced less per course of therapy than all available nicotine replacement therapies.*

Glaxo Wellcome Inc., a subsidiary of London-based Glaxo Wellcome plc., is a leading research-based pharmaceutical company located in Research Triangle Park, N.C.

Footnote: Habitrol(R) (nicotine transdermal system) is a registered trademark of Ciba-Geigy Corporation.

*Price charged by Glaxo Wellcome to wholesalers as of 5/1/97; retail costs will vary based on shortest duration of treatment and lowest dose recommended by manufacturer.

SOURCE Glaxo Wellcome Inc.

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