New Drugs Approved to Treat Chronic Alcoholism and Opioid Dependence

Mylan N.V. and Mylan, Inc. announced the U.S. launch of Disulfiram Tablets USP, 250 and 500 mg, which is the generic version of Odyssey Pharmaceutical’s Antabuse®. Mylan received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for this product, which is an aid in the management of select patients with chronic alcoholism who want to remain in a state of enforced sobriety so that supportive and psychotherapeutic treatment may be applied to the best advantage.

The companies also announced the U.S. launch of Buprenorphine Hydrochloride Sublingual Tablets, 2 and 8 mg, which is the generic version of Reckitt Benckiser’s Subutex® Sublingual Tablets. Mylan received final approval from the FDA for its ANDA for this product, which is indicated for the treatment of opioid dependence and is preferred for induction.

Saxenda® Approved for Chronic Weight Management

Novo Nordisk announced that the Food and Drug Administration approved the new drug application for Saxenda® (liraglutide [recombinant DNA origin] injection), the first once-daily glucagon-like peptide-1 receptor agonist for chronic weight management. Saxenda is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in obese or overweight adults in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia).

In the United States, approximately one third of adults are obese, leaving them at risk of myriad conditions that can affect their overall health. Current guidelines recognize that a sustained weight loss of 5% to 10% provides significant health benefits for obese adults.

Saxenda was evaluated in the SCALE™ (Satiety and Clinical Adiposity—Liraglutide Evidence in Nondiabetic and Diabetic Adults) phase 3 clinical trial program, which included more than 5,000 participants who were obese or overweight with comorbidities. Trial data showed that Saxenda, in combination with a reduced-calorie diet and increased physical activity, resulted in significantly greater weight loss than diet and physical activity alone.


Do You Have Any Product News to Share?

JPN would like to hear about it.

Please forward pertinent information to:
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