



FOR IMMEDIATE RELEASE

Wilmington Pharmaceuticals Receives FDA Approval for Orally Disintegrating Metoclopramide Tablet

Product Licensed to Salix Pharmaceuticals

WILMINGTON, NC (September 9, 2009)—Wilmington Pharmaceuticals announced today the U.S. Food and Drug Administration (FDA) has granted marketing approval for METOZOLV™ ODT (metoclopramide HCl), an orally disintegrating formulation of metoclopramide for the treatment of gastroesophageal reflux disease (GERD) and diabetic gastroparesis. Wilmington has licensed METOZOLV ODT to Salix Pharmaceuticals, Inc., a specialty pharmaceutical company with a focus on gastrointestinal disorders.

Wilmington Pharmaceuticals designed METOZOLV ODT to improve the delivery mode for patients who have difficulty swallowing pills or liquids due to their disease state. Orally disintegrating METOZOLV ODT tablets rapidly melt* on the tongue, thereby eliminating the need for swallowing pills with water, according to Eugene Haley, founder and CEO of Wilmington Pharmaceuticals.

“We are extremely pleased to have achieved a significant milestone, the approval of a patient-friendly formulation of an established drug that addresses the needs of patients who cannot swallow traditional tablets,” Haley said. “As developers of rapid-dissolve formulations for proven drugs, we provide our industry partners with significant potential for commercial gain without typical risks, costs, and time commitments associated with new drug development.”

Salix Pharmaceuticals will market METOZOLV ODT under a licensing agreement with Wilmington Pharmaceuticals. METOZOLV ODT is indicated for relieving symptoms in adults with acute and recurrent diabetic gastroparesis and for short-term therapy (4-12 weeks) in adults with symptomatic, documented GERD that fails to respond to conventional therapy.

“METOZOLV ODT offers a medically important option to physicians and patients,” said Carolyn Logan, CEO of Salix Pharmaceuticals. “We are delighted to bring a patient-friendly formulation of this widely prescribed product to market.”

“Wilmington Pharmaceuticals has proven to be a very reliable and efficient partner in the development of this important new dosage form of metoclopramide,” Logan added.

METOZOLV ODT represents the first approved drug among an array of candidates that Wilmington Pharmaceuticals is reformulating with rapid-dissolve technology. The company identifies well-established drugs to combine with rapid-dissolve delivery technologies and then licenses the drugs to pharmaceutical partners. Wilmington's seasoned pharmaceutical executives lead an integrated network of industry experts who seamlessly execute the diverse strategies required to develop and commercialize each product.

“We take proven drugs and enhance their delivery to increase patient convenience and compliance,” said David Burns, Wilmington's vice president of development and manufacturing. “We have assembled an extremely experienced and capable team that has facilitated our success in obtaining approval for METOZOLV ODT within an 18-month time frame, and the team is now developing additional products for approval.”

IMPORTANT SAFETY INFORMATION

Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. The risk of developing tardive dyskinesia increases with the duration of treatment and the total cumulative dose. Metoclopramide therapy should be discontinued in patients who develop signs or symptoms of tardive dyskinesia. There is no known treatment for tardive dyskinesia. In some patients, symptoms may lessen or resolve after metoclopramide treatment is stopped.

Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risk of developing tardive dyskinesia.

METOZOLV™ ODT (metoclopramide HCl) is indicated as short-term therapy for adults with symptomatic, documented gastroesophageal reflux disease (GERD) who fail to respond to conventional therapy and for the relief of symptoms associated with acute and recurrent diabetic gastroparesis (diabetic gastric stasis) in adults. Therapy should not exceed 12 weeks in duration. METOZOLV ODT is contraindicated in patients with intestinal obstruction, hemorrhage, or perforation; pheochromocytoma; known sensitivity or intolerance to metoclopramide; epilepsy; or are receiving concomitant medications with extrapyramidal reactions. METOZOLV ODT should be used with caution in patients showing acute dystonic reactions, drug-induced Parkinsonism, or other extrapyramidal symptoms; neuroleptic malignant syndrome; with a prior history of depression; hypertension; congestive heart failure and ventricular arrhythmia. Patients may experience withdrawal symptoms after stopping the use of METOZOLV ODT.

In clinical studies, the most frequently reported adverse events ($\geq 2\%$ occurrence) were headache, nausea, fatigue, somnolence, and vomiting.

About Wilmington Pharmaceuticals

Wilmington Pharmaceuticals develops and out-licenses patient-friendly, fast-dissolving formulations of established medications to treat pain, cardiac conditions, and central nervous system conditions. The company engages a highly skilled alliance of experts in clinical, regulatory, manufacturing, and other key areas to achieve rapid and cost-effective approval and commercialization of its products. This unique corporate model minimizes regulatory risks while maximizing economic opportunity (www.wilmingtonpharma.com).

About Salix Pharmaceuticals

Salix Pharmaceuticals, Inc., headquartered in Morrisville, North Carolina, develops and markets prescription pharmaceutical products for the treatment of gastrointestinal diseases. Salix's strategy is to in-license late-stage or marketed proprietary therapeutic drugs, complete any required development and regulatory submission of these products, and market them through the Company's gastroenterology specialty sales and marketing team.

Please Note: Materials provided herein contain projections and other forward-looking statements regarding future events. Such statements are only predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include the following, among others: market acceptance for approved products; reliance on licensors such as Salix to sell products; reliance on licensors of key technology, specifically Catalent Pharma Solutions for Zydys[®]; intellectual property and competitive risks; and the unpredictable nature of drug development and regulatory review.

*METOZOLV ODT disintegrates on the tongue in a median of 53.5 seconds (mean \pm standard deviation, 76.8 \pm 110.6 seconds).¹

¹METOZOLV ODT (metoclopramide HCl) Prescribing Information

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