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Welchol® (colesevelam HCl) Receives FDA Approval to Lower LDL Cholesterol in Pediatric Patients with Heterozygous Familial Hypercholesterolemia

Welchol for Oral Suspension Also Approved by FDA

Parsippany, NJ (October 07, 2009) – Daiichi Sankyo, Inc. (DSI) announced today that the U.S. Food and Drug Administration (FDA) has approved the supplemental new drug application (sNDA) for Welchol® (colesevelam HCl) to be used as an adjunct to diet and exercise for the reduction of elevated low-density lipoprotein cholesterol (LDL-C) in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia (heFH) alone or in combination with a statin after failing an adequate trial of diet therapy. Originally approved in 2000 for LDL-C lowering and in 2008 for A1C reduction in adults, Welchol is approved as an adjunct to diet and exercise to reduce elevated LDL-C in adults with primary hyperlipidemia and improve glycemic control in adults with type 2 diabetes mellitus.

Familial hypercholesterolemia (FH) is a genetic disorder resulting in elevated LDL cholesterol and increased risk of cardiovascular disease (CVD).[1] There are 10 million people with FH worldwide, the majority of whom have heFH.[2]

"The FDA approval of Welchol for children with inherited high cholesterol provides another important treatment option for these children, whose elevated LDL cholesterol puts them at increased risk for cardiovascular disease*," said Evan A. Stein, MD, PhD, Director, Metabolic & Atherosclerosis Research Center, Cincinnati, OH. "The pivotal trial of Welchol in this pediatric patient population demonstrated that Welchol, as monotherapy or when combined with a statin, significantly reduced LDL-C."

The approval of Welchol for pediatric patients with heFH is based on data from an eight-week, multi-center, randomized, placebo-controlled clinical study, which evaluated the efficacy of Welchol tablets (1.875 or 3.75 g/d) as monotherapy or in combination with a statin. The study was conducted with boys and postmenarchal girls 10-17 years of age, who were either treatment naïve or on stable background statin therapy. The most commonly reported adverse reactions reported in >/= 2 percent of patients – and more commonly than those given placebo – were nasopharyngitis, headache, fatigue, creatine phosphokinase increase, rhinitis and vomiting.[3]

Welchol for Oral Suspension

The FDA also approved Welchol® (colesevelam HCl) for Oral Suspension, providing an alternative to the current tablet formulation. Welchol for Oral Suspension is indicated as an adjunct to diet and exercise to improve both glycemic control in adults with type 2 diabetes mellitus, and to reduce elevated LDL cholesterol in adults with primary hyperlipidemia (Fredrickson Type IIa) as monotherapy or in combination with a hydroxymethyl-glutaryl-coenzyme A (HMG CoA) reductase inhibitor (a statin). Welchol for Oral Suspension is also indicated for use as an adjunct to diet and exercise for the reduction of elevated LDL-C in boys and post-menarchal girls, 10 to 17 years of age, with heFH alone or in combination with a statin after failing an adequate trial of diet therapy. The recommended dose of Welchol for Oral Suspension is one 3.75 gram packet once daily.

About Welchol

Welchol is indicated as an adjunct to diet and exercise to improve both glycemic control in adults with type 2 diabetes mellitus, and to reduce elevated LDL cholesterol in adults with primary hyperlipidemia (Fredrickson Type IIa) alone or in combination with a statin. In addition, Welchol is indicated as an adjunct to diet and exercise for the reduction of elevated low-density lipoprotein cholesterol (LDL-C) in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia (heFH) alone or in combination with a statin after failing an adequate trial of diet therapy. Welchol should not be used for the treatment of type 1 diabetes or for the treatment of diabetic ketoacidosis. Welchol has not been studied in type 2 diabetes as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor and has not been extensively studied in combination with thiazolidinediones. Welchol has not been studied in Fredrickson Type I, III, IV, and V dyslipidemias. Welchol has not been studied in children younger than 10 years of age or in pre-menarchal girls. Welchol is not approved in children with type 2 diabetes mellitus.

*The effect of Welchol on cardiovascular morbidity and mortality has not been determined.

IMPORTANT INFORMATION ABOUT WELCHOL (**colesevelam HCl)**

Indications

Welchol is indicated as an adjunct to diet and exercise to:

- reduce elevated low-density lipoprotein cholesterol (LDL-C) in patients with primary hyperlipidemia (Fredrickson Type IIa) as monotherapy or in combination with an hydroxymethyl-glutaryl-coenyme (HMG CoA) reductase inhibitor
- reduce LDL-C levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia, as monotherapy or in combination with a statin after failing an adequate trial of diet therapy
- improve glycemic control in adults with type 2 diabetes mellitus

Important Limitations of Use

- Welchol should not be used for the treatment of type 1 diabetes or for the treatment of diabetic ketoacidosis
- Welchol has not been studied in type 2 diabetes as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor and has not been extensively studied in combination with thiazolidinediones
- Welchol has not been studied in Fredrickson Type I, III, IV, and V dyslipidemias
- Welchol has not been studied in children younger than 10 years of age or in premenarchal girls

Contraindications

Welchol is contraindicated in individuals with bowel obstruction, those with serum triglyceride (TG) concentrations of >500 mg/dL, or with a history of hypertriglyceridemia-induced pancreatitis.

Warnings and Precautions

The effect of Welchol on cardiovascular morbidity and mortality has not been determined.

Welchol can increase serum TG concentrations particularly when used in combination with sulfonylureas or insulin. Caution should be exercised when treating patients with TG levels >300 mg/dL.

Welchol may decrease the absorption of fat-soluble vitamins A, D, E and K. Patients on vitamin supplements should take their vitamins at least 4 hours prior to Welchol. Caution should be exercised when treating patients with a susceptibility to vitamin K or fat-soluble vitamin deficiencies.

Caution should also be exercised when treating patients with gastroparesis, gastrointestinal motility disorders, major gastrointestinal tract surgery, and when treating patients with dysphagia and swallowing disorders.

Welchol reduces gastrointestinal absorption of some drugs. Drugs with a known interaction with colesevelam, especially those with a narrow therapeutic index, should also be administered at least 4 hours prior to Welchol. Drugs that have not been tested for interaction with colesevelam, especially those with a narrow therapeutic index, should also be administered at least 4 hours prior to Welchol. Alternatively, the physician should monitor drug levels of the coadministered drug.

To avoid esophageal distress, Welchol for Oral Suspension should not be taken in its dry form.

Due to tablet size, Welchol for Oral Suspension is recommended for, but not limited to, use in the pediatric population as well as in any patient who has difficulty swallowing tablets.

Phenylketonurics: Welchol for Oral Suspension contains 48 mg phenylalanine per 3.75 gram dose.

Adverse Reactions

In clinical trials, the adverse reactions observed in ≥2% of patients, and more commonly with Welchol than placebo, regardless of investigator assessment of causality seen in:

- Adults with Primary Hyperlipidemia were: constipation (11.0% vs 7.0%), dyspepsia (8.3% vs 3.5%), nausea (4.2% vs 3.9%), accidental injury (3.7% vs 2.7%), asthenia (3.6% vs 1.9%), pharyngitis (3.2% vs 1.9%), flu syndrome (3.2% vs 3.1%), rhinitis (3.2% vs 3.1%) and myalgia (2.1% vs 0.4%).

- Pediatric patients with heFH primary hyperlipidemia were: nasopharyngitis (6.2% vs 4.6%), headache (3.9 vs 3.1%), fatigue (3.9% vs 1.5%), creatine phosphokinase increase (2.3% vs 0.0%), rhinitis (2.3% vs 0.0%) and vomiting (2.3% vs 1.5%).

- Adult patients with Type 2 Diabetes were: constipation (8.7% vs 2.0%), nasopharyngitis (4.1% vs 3.6%), dyspepsia (3.9% vs 1.4%), hypoglycemia (3.0% vs 2.3%), nausea (3.0% vs 1.4%) and hypertension (2.8% vs 1.6%).

  Post-marketing experience: Due to the voluntary nature of these reports it is not possible to reliably estimate frequency or establish a causal relationship.
- Increased seizure activity or decreased phenytoin levels have been reported in patients receiving phenytoin concomitantly with Welchol.

- Reduced International Normalized Ratio (INR) has been reported in patients receiving warfarin concomitantly with Welchol.

- Elevated thyroid-stimulating hormone (TSH) in patients receiving thyroid hormone replacement therapy.

Pregnancy

Welchol is Pregnancy Category B.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For more information on Welchol, call 877-4-DSPROD (877-431-7763), or go to the Welchol web

site at www.Welchol.com. Please visit http://www.welchol.com/pdf/Welchol_PI.pdf for full Prescribing Information on Welchol.

About Daiichi Sankyo, Inc.

Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is the U.S. subsidiary of Tokyo-based Daiichi Sankyo Co., Ltd., which is a global pharmaceutical innovator. The headquarters company was established in 2005 from the merger of two leading Japanese pharmaceutical companies. This integration created a more robust organization that allows for continuous development of novel drugs for patients around the world. A central focus of Daiichi Sankyo's research and development is cardiovascular disease, including therapies for dyslipidemia, hypertension, diabetes and acute coronary syndrome. Also important to the company is the discovery of new medicines in the areas of infectious diseases, cancer, bone and joint diseases, and immune disorders. For more information, visit www.dsi.com.

References

1. Centers For Disease Control and Prevention, Diagnosis and Treatment Program for Familial Hypercholesterolemia. http://www.cdc.gov/prc/research-projects/special-interest-projects/diagnosis-treatment-familial-hypercholesterolemia.htm. Site accessed June 23, 2009.
2. Civeira F et al. Guidelines for the diagnosis and management of heterozygous familial hypercholesterolemia. *Atherosclerosis*. 2004; 173: 55-68.
3. Stein EA et al. Colesevelam HCl: efficacy and safety in pediatric subjects with heterozygous familial hypercholesterolemia. Poster presented at the American Heart Association's (AHA) Annual Scientific Sessions 2008; November 8-12, 2008, New Orleans, LA.

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