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New Data Demonstrate Welchol® (colesevelam HCl) Significantly Improved Lipid and Glycemic Measures in Patients with High LDL Cholesterol and Prediabetes

Parsippany, NJ (April 23, 2010) – Results of a new study showed that Welchol® (colesevelam HCl) 3.75 g/d significantly improved lipid and glycemic measures in patients with high LDL cholesterol and prediabetes (impaired fasting glucose and/or impaired glucose tolerance). The randomized, placebo-controlled, double-blind study was presented today at the American Association of Clinical Endocrinologists (AACE) 19th Annual Meeting and Clinical Congress in Boston.[1] These data are consistent with previous studies that have shown Welchol to be safe and effective in lowering A1C, fasting plasma glucose and low-density lipoprotein cholesterol (LDL-C) in adult patients with type 2 diabetes.[2]

"These new findings are important because they provide valuable information on the effects of Welchol to significantly reduce LDL cholesterol, fasting plasma glucose, and A1C levels in patients at high risk for developing type 2 diabetes," said Yehuda Handelsman, MD, FACP, FACE, Medical Director of the Metabolic Institute of America in Tarzana, Calif. and investigator of the study. "The evaluation of Welchol in this high risk population underscores recent guidelines established by AACE, which recommended physicians target and treat underlying disorders such as high cholesterol and elevated glucose levels in people with prediabetes."[3]

Approximately 57 million adults in the U.S. have impaired fasting glucose and/or impaired glucose tolerance, which puts them at a three to 10 times higher risk of developing type 2 diabetes and a 1.5 times greater risk of cardiovascular disease.[3,4,5] A recent position statement from the American Diabetes Association (ADA) stated that individuals with an A1C level of 5.7 to 6.4 percent are considered to have prediabetes and are at high risk for developing type 2 diabetes.[6] In patients diagnosed with type 2 diabetes, more than 50 percent also have elevated LDL cholesterol.[7]

About the Study

Poster #403 – Colesevelam HCl to Treat Hypercholesterolemia and Improve Glycemia in Prediabetes: A Randomized, Prospective Study[1,8]

This 16-week, randomized, placebo-controlled, double-blind, multinational study evaluated patients aged 18 to 79 years with high LDL cholesterol and prediabetes, who met the following criteria: LDL cholesterol levels ≥100 mg/dL; triglycerides <500 mg/dL; 2-hour post-oral glucose tolerance test (OGTT) glucose ≥140 mg/dL to <200 mg/dL; and/or fasting plasma glucose ≥110 to ≤125 mg/dL. A total of 216 patients were randomized to receive Welchol (colesevelam HCl) (3.75 g per day) or matching placebo. The primary endpoint of the study was the percent change in LDL cholesterol from the start of the study to week 16 with last observation carried forward. Secondary endpoints included changes in other lipid parameters, fasting plasma glucose, A1C, 2-hour post-OGTT glucose from the start of the study to week 16, as well as attainment of LDL cholesterol goal targets.

The study found that after 16 weeks of treatment, Welchol compared with placebo resulted in a statistically significant mean reduction of LDL cholesterol levels (-13.9 vs. +1.7 percent; mean treatment difference of -15.6 percent), mean non-HDL cholesterol levels (-8.4 vs. +0.7 percent; mean treatment difference of -9.1 percent), and mean apoliproprotein B levels (-7.5 vs. +0.6 percent; mean treatment difference of -8.1 percent), respectively, $p<0.001$. Welchol also improved glycemic levels compared with placebo, with a significant mean reduction in A1C levels (-0.12 vs. -0.03 percent; mean treatment difference of -0.10 percent; $p=0.02$) and significant reduction in median fasting plasma glucose levels (-4.0 mg/dL vs. -2.0 mg/dL; median treatment difference of -2.0 mg/dL; $p=0.02$). Treatment with Welchol increased triglyceride levels relative to placebo (median treatment difference: 14.3 percent; $p<0.001$).

Significantly more patients attained target levels for LDL cholesterol with Welchol compared with placebo at week 16: LDL cholesterol <100 mg/dL (29 vs. 11 percent; $p<0.001$). In addition, more patients receiving Welchol compared with placebo had A1C levels <6% (37 vs. 25 percent; $p=0.05$) and fasting plasma glucose levels <100 mg/dL (normalization of glucose) (40 vs. 23 percent; $p=0.06$). In the study, Welchol was well-tolerated and patients did not gain weight. One case of hypoglycemia was reported in each treatment group. The frequency of treatment-emergent adverse events was similar in the Welchol and placebo groups (53 vs. 58 percent, respectively). The drug-related adverse events were largely gastrointestinal in nature (constipation, diarrhea and indigestion). There were no patient deaths in the study. Two patients in both groups reported a serious adverse event – erectile dysfunction and polycystic ovaries for the two patients receiving Welchol – but none were considered related to the study drug or resulted in study withdrawal.

About Welchol

Approved in 2000 to lower LDL cholesterol and in 2008 as add-on therapy for glycemic control in adults, Welchol is approved by the U.S. Food and Drug Administration (FDA) as an adjunct to diet and exercise to reduce elevated LDL-C and improve glycemic control in adults with primary hyperlipidemia

and type 2 diabetes, two chronic health conditions. 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 available in two formulations, Welchol tablets and Welchol® for Oral Suspension.

In clinical studies of adult patients with type 2 diabetes, Welchol lowered A1C, fasting plasma glucose and LDL-C, important risk factors for cardiovascular disease.* In clinical studies of patients with elevated LDL-C, Welchol lowered LDL-C when used as monotherapy, when added to statin therapy, or as initial combination with statin therapy.[2]

*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.

IMPORTANT INFORMATION ABOUT WELCHOL (colesevelam HCl), continued

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.

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

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 (877-437-7763), or go to the Welchol web

site at www.Welchol.com.

For patients having difficulty affording their Welchol (colesevelam HCl) medication, please call the Daiichi Sankyo Open Care Patient Assistance Program at 1-866-268-7327 for more information or visit www.dsi.com.

About Daiichi Sankyo

In keeping with its vision of becoming a "Global Pharma Innovator," the Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of customers in both developed and emerging markets. While maintaining its portfolio of marketed pharmaceuticals for hypertension, hyperlipidemia, and bacterial infections, the Group is engaged in the development of treatments for thrombotic disorders and focused on the discovery of novel oncology and cardiovascular-metabolic therapies. Furthermore, the Daiichi Sankyo Group has created a "Hybrid Business Model," which will respond to market and customer diversity and optimize growth opportunities across the value chain. For more information, please visit www.daiichisankyo.com.

Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is the U.S. subsidiary of Daiichi Sankyo Company, Ltd. For more information on Daiichi Sankyo, Inc., please visit www.dsi.com.

References

1. Handelsman Y et al. Colesevelam HCL to Treat Hypercholesterolemia and Improve Glycemia in Prediabetes: A Randomized, Prospective Study. Poster at the American Association of Clinical Endocrinologists (AACE) 19th Annual Meeting and Clinical Congress , Boston (April 21-25, 2010).
2. Welchol Product Information. Available at: http://www.welchol.com/utilities/product_info.html.
3. Garber AJ, Handelsman Y, Einhorn D, et al. Diagnosis and management of prediabetes in the continuum of hyperglycemia: when do the risks of diabetes begin? A consensus statement from the American College of Endocrinology and the American Association of Clinical Endocrinologists. *Endocrine Practice* 2008; 14: 933-946.
4. Centers for Disease Control and Prevention. National Diabetes Fact Sheet: general information and national estimates on diabetes in the United States, 2007. In: US Department of Health and Human Services, ed. Atlanta, GA, 2008.
5. American Diabetes Association. Pre-diabetes FAQs. Available at: http://www.diabetes.org/diabetes-basics/prevention/pre-diabetes/pre-diabetes-faqs.html.
6. American Diabetes Association. Diagnosis and classification of diabetes mellitus. *Diabetes Care*. 2010; 33: S62-S69.
7. Cheung BMY et al. Diabetes Prevalence and Therapeutic Target Achievement in the United States, 1999 to 2006. *The American Journal of Medicine*. 2009; 122: 443-453.
8. Daiichi Sankyo, Inc. Data on File.

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