EMBARGOED: 10 AM EDT, June 26, 2010

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New Data Demonstrated Efficacy and Safety of Initial Combination Therapy with Welchol® (colesevelam HCl) and Metformin in Drug-Naïve Adult Type 2 Diabetes Patients

Treatment with Welchol and Metformin Significantly Improved Patients' Glycemic and Lipid Control

Parsippany, NJ (June 26, 2010) – Results of a new study demonstrated that initial combination therapy with Welchol® (colesevelam HCl) 3.75 g/d and metformin (initiated at 850 mg/d; uptitrated to 1700 mg/d thereafter) significantly improved glycemic and lipid control in drug-naïve adult type 2 diabetes patients with high LDL cholesterol (LDL-C). In the study, treatment with Welchol plus metformin significantly reduced mean A1C levels by 1.1 percent and LDL-C levels by 21 percent. In addition, approximately two-thirds of patients who received Welchol plus metformin achieved the American Diabetes Association (ADA)'s glycemic goal of A1C levels less than 7 percent, which was statistically significant compared with metformin plus placebo alone.[1] Results of the randomized, double-blind, placebo-controlled study were presented today at the 70th Scientific Sessions of the ADA in Orlando.

"In this study, early intervention with Welchol and metformin significantly reduced A1C and LDL cholesterol levels, two important risk factors for cardiovascular disease, in drug-naïve adult type 2 diabetes patients with high cholesterol," said Yehuda Handelsman, MD, FACP, FACE, Medical Director of the Metabolic Institute of America in Tarzana, Calif. and investigator of the study. "Notably, these data indicate that initial combination therapy with Welchol and metformin may represent a safe and effective option to help patients with type 2 diabetes reach glycemic and lipid goals."

About 23.6 million, or 8 percent of people in the United States, have diabetes, and approximately 90 to 95 percent of people diagnosed with diabetes have type 2 diabetes.[2] The ADA and the American College of Cardiology emphasize that it is critical to reduce both A1C and LDL cholesterol levels, as more than 50 percent of adults with type 2 diabetes also have elevated LDL cholesterol, greatly increasing their risk of cardiovascular disease.[3,4,5] The effect of Welchol on cardiovascular morbidity and mortality has not been determined.

"As the only medication approved to treat both A1C and LDL-C in adults with type 2 diabetes and primary hyperlipidemia, Welchol addresses both of these chronic health conditions and provides physicians with a unique therapeutic approach for the comorbid patient," said Jay M. Feingold, MD, PhD, Vice President of Medical Affairs at Daiichi Sankyo, Inc. "We are encouraged by these study results, which reinforce the benefits of Welchol for treating adult patients with type 2 diabetes and/or elevated LDL cholesterol."

About the Study (Posters #684 and #633)[1,6]

The randomized, double-blind, placebo-controlled, parallel-group study was conducted at approximately 38 sites within the U.S., Mexico, Colombia, and India, and included a three-week screening period to confirm disease diagnosis followed by 16 weeks of randomized treatment. The study evaluated patients aged 18 to 79 years diagnosed with type 2 diabetes (A1C 6.5 to 10.0 percent, inclusive) and who were drug-naïve – defined as never having received treatment for their diabetes, or not having received diabetes medication for three months prior to screening – with LDL cholesterol levels greater than or equal to 100 mg/dL and triglyceride levels less than 500 mg/dL. In total, 286 patients with type 2 diabetes and high cholesterol were randomized to receive either Welchol (colesevelam HCl) 3.75 g/d (n=145) or placebo (n=141) along with open-label metformin (initiated at 850 mg/d; uptitrated to 1700 mg/d thereafter). Mean baseline A1C levels were 7.8 percent in the Welchol plus metformin group and 7.5 percent in the metformin plus placebo group.

The study found that initial combination therapy with Welchol and metformin reduced mean A1C levels by 1.1 percent compared with patients receiving metformin plus placebo (-0.8 percent), resulting in a mean treatment difference of -0.3 percent ($p<0.01$). The study also showed that 67 percent of patients (n=66) achieved the A1C target of less than 7 percent with Welchol plus metformin, compared with 56 percent of patients (n=53) receiving metformin plus placebo, a statistically significant difference ($p<0.01$). Additionally, 48 percent of patients (n=61) in the Welchol group attained LDL cholesterol less than 100 mg/dL compared with 18 percent of patients (n=24) in the metformin plus placebo group ($p<0.0001$).

Welchol in combination with metformin also resulted in significantly greater mean reductions in LDL cholesterol levels (16 percent), mean total cholesterol levels (6 percent), mean non-HDL cholesterol (8 percent), mean apolipoprotein B (8 percent), and median high sensitivity C-reactive protein (hs-CRP) (17 percent) compared with patients treated with metformin plus placebo, ($p<0.01$ for all). In the study, Welchol plus metformin increased triglycerides by 19 percent ($p<0.001$) compared with metformin plus placebo.

Results from a safety analysis of this study showed that initial combination therapy with Welchol and metformin was well-tolerated and had a safety profile similar to that of metformin monotherapy. Compliance with the individual treatment components was greater than 90 percent for both groups. In patients receiving Welchol plus metformin, the most common gastrointestinal adverse events were diarrhea (12 percent) and nausea (12 percent); the most common non-gastrointestinal adverse events

were headache (8 percent), influenza (8 percent), and dizziness (6 percent). Mild hypoglycemia was reported in two patients treated with Welchol (colesevelam HCl) and metformin compared with three patients receiving metformin and placebo. By the end of the study, weight decreased by 2.1 kg in each group.

About Welchol

Approved in 2000 to lower LDL cholesterol and in 2008 as add-on therapy for glycemic control in adults with type 2 diabetes, 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 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.[7]

*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 hydroxymethylglutaryl-coenzyme (HMG CoA) reductase inhibitor (statin)
- improve glycemic control in adults with type 2 diabetes mellitus

Important Limitations of Use

- Welchol should not be used for glycemic control in 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

Contraindications

Welchol is contraindicated in individuals with a history of 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.

IMPORTANT INFORMATION ABOUT WELCHOL (colesevelam HCl), continued

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, a history of 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 (cyclosporine, glyburide, levothyroxine, and oral contraceptives [ethinyl estradiol, norethindrone]) should 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 co-administered 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, 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%)
- 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) has been reported 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, Inc. 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. Rosenstock J et al. Initial Combination Therapy with Metformin + Colesevelam Safely Achieves Glycemic and Lipid Goals with Less Diarrhea in Early Type 2 Diabetes Mellitus. Poster at the 70th Scientific Sessions of the American Diabetes Association (ADA), Orlando (June 25-29, 2010).
2. Center for Disease Control, National Diabetes Fact Sheet 2007. http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2007.pdf. Accessed June 1, 2010.
3. Brunzell JD, Davidson M, Furberg CD, et al. Lipoprotein management in patients with cardiometabolic risk: consensus statement from the American Diabetes Association and the American College of Cardiology Foundation. *Diabetes Care*. 2008;31(4):811-822.
4. Buse JB, Ginsberg HN, Bakris GL, et al. Primary Prevention of Cardiovascular Diseases in People With Diabetes Mellitus: A Scientific Statement From the American Heart Association and the American Diabetes Association. *Circulation*. 2007;115:114-126. http://circ.ahajournals.org/cgi/content/full/115/1/114. Accessed June 1, 2010.
5. 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.
6. Abby SL et al. The Safety and Tolerability of Metformin + Colesevelam in Drug-Naive Patients with Early Type 2 Diabetes Mellitus. Poster at the 70th Scientific Sessions of the American Diabetes Association (ADA), Orlando (June 25-29, 2010).
7. Welchol Prescribing Information. Available at: http://www.welchol.com/pdf/Welchol_PI.pdf.

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