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Welchol™ Lowered A1C by A Mean 1 Percent or Greater When Added to Metformin-, Insulin-, or Sulfonylurea-Based Therapy in 47 Percent of Patients Evaluated

Post-hoc analysis of pivotal studies presented at the National Lipid Association's Annual Scientific Sessions

Parsippany, NJ (May 29, 2008) – Daiichi Sankyo, Inc., announced today that data from post-hoc analyses of three pivotal studies demonstrated that the addition of Welchol™, (colesevelam HCl) to common diabetes treatment regimens can lower A1C in patients with type 2 diabetes mellitus by 1% or greater. The analyses included all patients receiving Welchol in these studies (n=512). Almost half (47%) of the patients in the analyses had a mean reduction in A1C of 1.04% and nearly a quarter (24%) had a mean reduction as great as 1.40%. Type 2 diabetes can put people at risk for serious health complications such as blindness, amputation and kidney failure.[1]

A second post-hoc analysis demonstrated that Welchol lowered A1C and LDL-cholesterol (LDL-C) levels consistently across type 2 diabetes patients, regardless of age, gender or race. These findings were included among five poster presentations by Daiichi Sankyo at the National Lipid Association (NLA) Annual Scientific Sessions.

The American Diabetes Association (ADA) recommends that people with type 2 diabetes control both blood glucose and cholesterol levels to reduce the risk of developing cardiovascular disease.[2] The National Cholesterol Education Program (NCEP) recommends that patients with type 2 diabetes keep their cholesterol levels in check and target an LDL-C goal of <100 mg/dL.[3] Despite this recommendation, nearly 40 percent of patients with type 2 diabetes have LDL-cholesterol levels greater than 130 mg/dL.[4] Welchol is the first and only therapy approved to treat both type 2 diabetes and high LDL-cholesterol.

"These findings are significant given the critical importance of achieving and maintaining A1C control," said Vivian A. Fonseca, Professor of Medicine and Pharmacology and Chief,

Section of Endocrinology, Tulane University Health Sciences Center, and a principal study investigator. “A patient’s A1C level is one of our primary markers in determining their risk of developing cardiovascular disease. These analyses show that adding Welchol to the most common type 2 diabetes regimens can help achieve additional A1C lowering across many different patient types.”

Several mechanisms have been proposed for the glucose-lowering effect of Welchol, including reductions in glucose absorption and effects on glucose metabolism via nuclear receptors in the intestine and/or the liver. The exact mechanism(s) is under investigation.

About the Analyses

For both analyses, data was extracted from three double-blind, placebo-controlled, pivotal Welchol trials involving 1,018 patients. Welchol was added to either metformin-, insulin- or sulfonylurea-based therapy in patients with inadequately controlled type 2 diabetes (A1C 7.5% to 9.5%). The mean baseline A1C of patients in these studies was 8.1% to 8.3%. The primary endpoint in the pivotal Welchol trials was mean change from baseline in A1C. Mean change in LDL-cholesterol was a secondary endpoint.

In the first post-hoc analysis, efficacy parameters included change from baseline in A1C. All patients receiving Welchol were pooled (N=512) and stratified based on individual A1C reductions (≥0.5%, ≥0.7%, and ≥1.0%) from baseline to study end. The results from the post-hoc analyses found that almost half (47%) of the patients achieving a reduction of ≥0.5% had a mean A1C reduction of 1.04% (P<0.001); 36% of patients achieving a reduction of ≥0.7% had a mean A1C reduction of 1.20% (P<0.001); and 24.1% achieving a reduction of ≥1.0% had a mean A1C reduction of 1.40% (P<0.001).

In the second post-hoc analysis, data from the pivotal studies were pooled and patients were stratified by age (≥65 and <65 years), gender, and race (Caucasian, Black, and Hispanic). Efficacy parameters included reductions in A1C and LDL-C across these subgroups.

Patients aged 65 or older had a 0.59% mean reduction in A1C (P<0.0001) and a mean reduction in LDL-C of 14.73 (P<0.0001), whereas patients younger than 65 had a 0.54% mean reduction in A1C (P<0.0001) and a mean reduction in LDL-C of 15.50 (P<0.0001). Regarding gender, male patients had a 0.60% mean reduction in A1C (P<0.0001) and a mean reduction in LDL-C of 14.49 (P<0.0001), while female patients had a mean reduction in A1C of 0.48% (P<0.0001) and a mean LDL-C reduction of 16.13% (P<0.0001).

When patients were stratified by race, all subgroups had comparable reductions in both A1C and LDL-C: Caucasian patients had a mean reduction in A1C of 0.48% (P<0.0001) and a mean reduction in LDL-C of 16.16 (P<0.0001); Black patients had a 0.77% mean reduction in A1C (P<0.0002) and a mean reduction in LDL-C of 19.64 (P<0.0001); and Hispanic patients had a 0.54% mean reduction in A1C (P<0.0001) and a mean reduction in LDL-C of 11.31 (P<0.0001).

IMPORTANT INFORMATION ABOUT WELCHOL

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-coenzyme A (HMG CoA) reductase inhibitor. Welchol is also indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Welchol should not be used for the treatment of type 1 diabetes or for the treatment of diabetic ketoacidosis. It 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 contraindicated in individuals with bowel obstruction, those with serum triglyceride (TG) concentrations of >500 mg/dL, or with a history of hypertriglyceridemia-induced pancreatitis.

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 (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.

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

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

Welchol is Pregnancy Category B.

For more information on Welchol, call 877-4-DSPROD (877-437-7763), or go to the Welchol web site at www.Welchol.com.

About Daiichi Sankyo, Inc.

Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is the U.S. subsidiary of Daiichi Sankyo Co., Ltd., one of Japan's leading pharmaceutical companies and a global leader in pharmaceutical innovation whose roots date back to 1899. The company is dedicated to the discovery, development and commercialization of innovative medicines that improve the lives of patients throughout the world. The primary focus of Daiichi Sankyo's research and development is cardiovascular disease, including therapies for dyslipidemia, hypertension, diabetes, and acute coronary syndrome. The company is also pursuing the discovery of new medicines in the areas of glucose metabolic disorders, infectious diseases, cancer, bone and joint diseases, and immune disorders. For more information, visit www.dsus.com.

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