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Data from Pooled Analyses Demonstrate Welchol, Combined with Metformin- or Sulfonylurea-Based Therapy, Significantly Lowers Blood Glucose in Adults with Type 2 Diabetes

First and Only Therapy Approved to Treat Both Type 2 Diabetes and High LDL-Cholesterol
Welchol Recently Added to ACE/AACE Road Maps

Parsippany, NJ (May 16, 2008) – Daiichi Sankyo, Inc. (DSI) announced today that data from two pooled analyses further demonstrate that Welchol™ (colesevelam HCl), in combination with metformin- or sulfonylurea-based therapy, significantly lowers blood glucose (as measured by A1C) in patients with type 2 diabetes mellitus who had failed to achieve glycemic control (ADA target of A1C <7%). These findings, presented at the American Association of Clinical Endocrinologists' (AACE) 17th Annual Meeting and Clinical Congress, are the latest in a series of diabetes-related milestones for Welchol. In April, DSI announced that Welchol was added to the American College of Endocrinology (ACE)/AACE "Road Maps to Achieve Glycemic Control in Type 2 Diabetes Mellitus."

The efficacy of Welchol compared to placebo was evaluated in patients receiving metformin-based or sulfonylurea-based therapy (either monotherapy or in combination with other antidiabetes therapy) in two separate pooled analyses of patients from three Welchol pivotal studies.* The addition of Welchol in patients on established metformin-based therapy demonstrated a significant mean A1C reduction of 0.50%, placebo-corrected change from baseline (mean baseline A1C was 8.2% for both Welchol and placebo). In a second pooled analysis, the addition of Welchol in patients on established sulfonylurea-based therapy demonstrated a mean reduction in A1C of 0.53%, placebo-corrected change from baseline (mean baseline A1C was 8.2% and 8.3% for Welchol and placebo, respectively).

"These analyses further demonstrate the potential benefit of adding Welchol to current common diabetes treatment regimens," said Vivian E. Fonseca, Professor of Medicine and Pharmacology and Chief, Section of Endocrinology, Tulane University Health Sciences Center, a principal investigator of the study. "This gives physicians an additional option when it comes to helping their patients lower their A1C levels."

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**For further information on Welchol clinical studies, please see prescribing information.*

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 and remains to be confirmed.

About the Analyses

A pooled analysis evaluated 696 patients on metformin-based therapy (monotherapy or combination with other antidiabetes agents) who received add-on treatment with Welchol 3.75 g/day (n=355) or placebo (n=341). Efficacy endpoints in this analysis included change from baseline in A1C and fasting plasma glucose (FPG). Lipids and weight were not analyzed in this pooled analysis, however, LDL-C was significantly reduced in each of the primary studies (*P*<0.001 vs. placebo). Weight did not significantly change with Welchol in any of the primary studies. The addition of Welchol to metformin-based therapy achieved a significant mean reduction in A1C levels of 0.42% while A1C increased by 0.08% in the placebo group, resulting in a placebo-corrected mean change from baseline of -0.50% (*P*<0.001). Fasting plasma glucose decreased by -4.6 mg/dL in the Welchol group and increased by 11.1 mg/dL in the group treated with placebo, resulting in a mean treatment difference of -15.7 mg/dL (*P*<0.001). Furthermore, the addition of Welchol to metformin therapy resulted in a significantly higher proportion of patients achieving a mean reduction in A1C of ≥0.7% (38.3% vs. 19.4%; *P*<0.001) or a reduction in FPG ≥30 mg/dL (30.1% vs. 22.0%; p=0.015), from baseline to endpoint versus the placebo.

A second pooled analysis evaluated 653 patients on sulfonylurea-based therapy (monotherapy or combination with other antidiabetes agents). Patients received add-on therapy with Welchol 3.75 g/day (n=326) or placebo (n=327). The addition of Welchol resulted in a mean A1C change from baseline of -0.35% (mean baseline A1C 8.2%) compared with placebo which had a mean increase of 0.18% (mean baseline A1C 8.3%), resulting in a mean treatment difference of -0.53% by study end (*P*<0.001). Fasting plasma glucose decreased by -1.4 mg/dL in the patients treated with Welchol and increased by 12.2 mg/dL in the placebo group, resulting in a mean treatment difference of -13.6 mg/dL (*P*<0.001). In addition, significantly more patients in the Welchol treatment group achieved a reduction in A1C ≥0.7% (35.0% vs. 16.5%; *P*<0.001) or FPG ≥30 mg/dL (29.1% vs. 21.7%; *P*=0.029), from baseline to endpoint versus the placebo group.

Welchol Added to AACE Road Maps

Daiichi Sankyo also recently announced that Welchol has been added to the American College of Endocrinology (ACE) and American Association of Clinical Endocrinologist's (AACE) 2008 "Road Maps to Achieve Glycemic Control in Type 2 Diabetes Mellitus". The Road Maps are updated regularly by ACE/AACE to provide physicians with the latest and most comprehensive treatment options for their patients with type 2 diabetes mellitus. Welchol is the first and only therapy approved to treat both type 2 diabetes and high LDL-cholesterol. This is the second major diabetes related milestone for Welchol this year, as Welchol was approved by the FDA for the treatment of type 2 diabetes in January.

"Welchol offers physicians a new treatment option that addresses two cardiovascular risk factors, high LDL-Cholesterol and blood glucose in patients with type 2 diabetes," said Sukumar Nagendran,

M.D., Senior Director, Diabetes and Metabolism, Daiichi Sankyo, Inc. "Cardiovascular risk factors are always of great concern to physicians treating type 2 diabetes patients, as they are at significantly greater risk for developing cardiovascular disease. The inclusion of Welchol in these Road Maps will enable more physicians to be aware of the potential impact of adding this unique product to their patients' treatment regimen."

It is estimated that half of all Americans have elevated blood cholesterol levels that can negatively impact their health and quality of life.[1] According to the National Healthcare Quality Report, nearly 40 percent of adults with high cholesterol also have type 2 diabetes.[2]

The ADA recommends that patients with type 2 diabetes target an A1C level of < 7 percent.[3] A1C is a common test for persistent hyperglycemia ("too much glucose in the blood"). Additionally, 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.[4] Despite this recommendation, nearly 40 percent of patients with type 2 diabetes have LDL cholesterol levels greater than 130 mg/dL.[5]

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.

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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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References

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