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Welchol[®] Added to the American College of Endocrinology/American Association of Clinical Endocrinologists "Road Maps to Achieve Glycemic Control in Patients with Type 2 Diabetes Mellitus"

First and Only Cholesterol Lowering Medication Approved to Reduce A1C and LDL Cholesterol Achieves New Diabetes Treatment Milestone

The attached is the press release issued by Daiichi Sankyo Inc.; US affiliate of DAIICHI SANKYO COMPANY LIMITED.



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First and Only Cholesterol Lowering Medication Approved to Reduce A1C and LDL Cholesterol Achieves New Diabetes Treatment Milestone

Parsippany, NJ (April 15, 2008) – Daiichi Sankyo announced today that Welchol[®] (colesevelam HCI) 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.

Welchol, which is indicated for use in combination with metformin, sulfonylureas, or insulin, was added to the combination therapy section of the Road Maps for treated patients with type 2 diabetes mellitus. This is the second major diabetes related milestone for Welchol this year. In January, Welchol was approved by the FDA for the treatment of type 2 diabetes. Welchol is also approved for lowering LDL-C in patients with primary hyperlipidemia.

The Road Maps are important tools for physicians. They are used by doctors to help achieve ACE/AACE Glycemic Control guideline recommendations in patients with type 2 diabetes mellitus and are intended to assist in the treatment of these patients, including those who have not reached their A1C goals. The Road Maps are based on clinical data and clinical applications and compliment ACE/AACE guidelines, which are updated every two to three years.

"The ACE/AACE Road Maps provide physicians with an important tool in providing treatment algorithms for their patients with diabetes," said Philip Levy, M.D., Clinical Professor, University of Medicine at the University of Arizona College, Road Map task force member. "The updates to the Road Maps provide critical new information to physicians so they can best treat and prevent diabetes in their patients and help them achieve their A1C goals."

Welchol was recently approved by the Food and Drug Administration (FDA) to improve glycemic control (measured as hemoglobin A1C) in adults with type 2 diabetes mellitus in combination with metformin, sulfonylureas, or insulin, either alone or in combination with other anti-diabetic agents. Welchol is now the first and only medication approved to reduce both glucose levels and low density lipoprotein cholesterol levels (LDL-C).

Marketed since 2000, Welchol, a bile acid sequestrant, is different from most other cholesterol-lowering drugs on the market because it is non-systemic, meaning that the body does not absorb it and it is eliminated without traveling to the liver or kidneys. Therefore, Welchol is not expected to have drug interactions via the cytochrome P450 pathway.

"Welchol offers physicians a new treatment option that addresses two cardiovascular risk factors, elevated 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."

For more information about Welchol, please visit <u>www.Welchol.com</u>.

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 $\geq 2\%$ 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 \geq 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 (877-431-7763), 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 <u>www.dsus.com</u>.

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