For Immediate Release
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Welchol™ (colesevelam HCl) Receives FDA Approval to Reduce Blood Glucose in Adults with Type 2 Diabetes

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

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Welchol™ (colesevelam HCl) Receives FDA Approval to Reduce Blood Glucose in Adults with Type 2 Diabetes

First and only medication approved to reduce both A1C and LDL cholesterol

Parsippany, NJ (January 18, 2008) – Daiichi Sankyo, Inc., announced today that the United States Food and Drug Administration (FDA) has approved Welchol™ (colesevelam HCl) 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). The ADA estimates that 20.8 million people in the United States have diabetes with more than 90 percentof these people having type 2 diabetes.[1] Forty percent of patients with type 2 diabetes also have high LDL-cholesterol[2]. Welchol is a new option that addresses both these chronic health conditions and provides physicians with a unique therapeutic approach for treating patients with type 2 diabetes.

Pivotal data presented at the American Diabetes Association's (ADA) 67th Annual Scientific Sessions in Chicago in June, 2007 demonstrated that Welchol can lower both A1C and LDL-C levels in patients with type 2 diabetes who were uncontrolled on a metformin-based regimen. Patients in the study were randomly assigned to two groups. The addition of Welchol was compared to the addition of placebo in patients on a metformin-based regimen. The addition of Welchol (n=79) to pre-existing metformin monotherapy achieved a significant mean reduction in A1C levels of 0.47 percentrelative to placebo ($p<0.0024$). Further, the total Welchol treatment group, when treated with either metformin monotherapy or metformin-combination therapy, achieved significantly greater reductions in A1C levels compared to placebo (mean reduction of 0.54%; $p<0.001$). The study further demonstrated that the total Welchol treatment group achieved significantly lower LDL-C levels compared to the placebo group (mean reduction of 15.9%; $p<0.001$).

In addition, two other pivotal studies showed similar results in A1C reductions when Welchol was added to either sulfonylurea-based therapy or insulin-based therapy. In patients with type 2 diabetes who were inadequately controlled on sulfonylurea-based therapy the addition of Welchol was shown to have a significant reductions in A1C (mean reduction of 0.54%; $p<0.001$) vs. placebo at week 26. In patients inadequately controlled with insulin, alone or in combination with other anti-diabetic agents, the addition of

Welchol was shown to have significant mean reduction in A1C (mean reduction of 0.50%; p<0.0001) vs. placebo.

"Welchol now offers physicians a treatment option that addresses two major cardiovascular risk factors; elevated LDL cholesterol and blood glucose in patients with type 2 diabetes" said Ronald B. Goldberg, MD, an investigator in the insulin and metformin pivotal studies and Professor of Medicine at the Division of Diabetes and Metabolism and Associate Director of the Diabetes Research Institute at the University of Miami, Miller School of Medicine in Florida. “Cardiovascular risk factors are of great concern because patients with type 2 diabetes have a significantly increased risk of developing cardiovascular disease. Once clinical cardiovascular disease develops, these patients have a poorer prognosis than normoglycemic patients.”

Since 2000, Welchol, a bile acid sequestrant, has been indicated, alone or in combination with a statin, for the reduction of elevated LDL-C in patients with primary hypercholesterolemia. It 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. Systemic medications, which include statins, fibrates and cholesterol absorption inhibitors, are those that are absorbed from the intestine into the bloodstream and travel throughout the body, specifically to the liver and/or kidneys.

Additionally, Welchol has demonstrated beneficial effects on other lipid parameters such as HDL-C and APO-B. Welchol has also been studied in combination with fenofibrate in patients with mixed dyslipidemia (Fredrickson Type IIb), and provided additional LDL-C reductions in these patients when added to a stable fenofibrate regimen. Welchol is not indicated for use in combination with fenofibrate or in the treatment of mixed dyslipidemia or lipid parameters other than LDL-C.

"We are excited by the opportunity to help more patients with chronic conditions reach their recommended health goals,” said Joseph P. Pieroni, President and CEO of Daiichi Sankyo, Inc. “This approval represents an important milestone for our growing U.S. organization and underscores our continued commitment to combating cardiovascular and metabolic diseases.”

People with diabetes face significantly higher risk of developing cardiovascular disease.[3] The ADA recommends that patients with type 2 diabetes target an A1C level of < 7%.[4] 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.[5] Despite this recommendation, nearly 40 percent of patients with type 2 diabetes have LDL cholesterol levels greater than 130 mg/dL.[6]

It is estimated that half of all Americans have elevated blood cholesterol levels that can negatively impact their health and quality of life.[7] According to the National Healthcare Quality Report, nearly 40 percent of adults with high cholesterol also have type 2 diabetes.[8]

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 surgeryand 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 (877-431-7763), 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., Japan's second largest pharmaceutical company and a global leader in pharmaceutical innovation since 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, please visit www.dsus.com.

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Please see package insert for full prescribing information.

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