

DAIICHI SANKYO, INC. ANNOUNCES FILING OF SUPPLEMENTAL NEW DRUG APPLICATION FOR WELCHOL IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS

Parsippany, NJ (January 2, 2007) – Daiichi Sankyo, Inc. announced today that it has filed a supplemental New Drug Application (sNDA) with the U.S. Food and Drug Administration (FDA) for WelChol® (colesevelam HCl) to improve glycemic control in patients with type 2 diabetes mellitus. If approved, WelChol will be the first LDL cholesterol lowering medication also indicated for improving glycemic control.

Clinical studies have shown that WelChol lowers A1C in patients with type 2 diabetes mellitus. One study, presented at the American Heart Association's (AHA) Scientific Sessions 2006 in Chicago, showed that WelChol, when added to insulin, demonstrated a mean A1C reduction of 0.5% compared to placebo (-0.41% vs. +0.09%, $p < 0.007$). A similar effect was demonstrated in an additional WelChol study presented at the American Diabetes Association's (ADA) 66th Annual Scientific Sessions. In this study, the **Glucose Lowering Effect Of WelChol Study (GLOWS)**, WelChol added to an oral antidiabetic therapy resulted in mean A1C reductions of 0.5% compared to placebo ($p = 0.0007$) and 1.0% in patients with A1C $\geq 8.0\%$ compared to placebo ($p = 0.002$).

"Every physician who treats diabetes is looking to lower A1C as effectively as possible, resulting in a constant lookout for improved combinations of therapy," said Ronald B. Goldberg, MD, Professor of Medicine, the Division of Diabetes and Metabolism and Associate Director, Diabetes Research Institute at the University of Miami Miller School of Medicine. "The same can be said for LDL-cholesterol as well. As a result, a compound that can help lower both of these important cardiovascular risk factors, A1C and LDL-cholesterol, can be of great benefit for many patients."

The ADA estimates that 20.8 million people in the United States have diabetes and over 90% of these have type 2 diabetes. The ADA recommends that patients with type 2 diabetes target an A1C level of $< 7\%$.¹ 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.²

"Given the prevalence of type 2 diabetes and high cholesterol and the number of patients who are not reaching goal, adding WelChol expands patients' treatment options," said Joseph P. Pieroni, President and CEO of Daiichi Sankyo, Inc. "Daiichi Sankyo strives to contribute to the health and well-being of people worldwide, particularly in cardiovascular care, and we will continue to investigate new applications of our therapies for patients' benefit."

A recent survey of physicians attending this year's annual AHA meeting further illuminates the prevalence of patients with high cholesterol and type 2 diabetes. HRA Research, a leading healthcare market research company specializing in the pharmaceutical industry, surveyed 100 physicians for their experience with addressing cholesterol and glycemic control. Half the physicians surveyed reported that over 60% of their type 2 diabetes patients also have high cholesterol, and over 80% of the physicians were extremely interested in a drug that could treat both conditions.³ Two-thirds of the physicians polled

indicated that over the next year they expect to increase their prescribing of combination therapy to lower both A1C and LDL-C.⁴ Two-thirds report that the recent update of ADA guidelines changed their treatment regimen. They now feel strongly that each possible drop in A1C levels is critical to the health of their type 2 diabetes patient.⁵

About WelChol

WelChol is indicated for LDL-C lowering and was approved by the U.S. Food and Drug Administration (FDA) for marketing in May 2000. WelChol is the top-selling branded drug in the bile acid sequestrants (BAS) class. WelChol 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-drug interactions via the cytochrome P-450 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.

WelChol is a prescription drug indicated alone or in combination with a statin, as an adjunct to diet and exercise for the reduction of elevated LDL cholesterol in patients with primary hypercholesterolemia (Fredrickson Type IIa) when the response to diet and exercise has been inadequate. Liver-function monitoring is not required with WelChol when used as monotherapy, and in combination with a statin, no additional liver-function monitoring is required beyond that for the prescribed statin alone.

In clinical trials with patients with primary hypercholesterolemia, when WelChol was given alone in addition to a low-fat diet and exercise, it was shown to reduce LDL cholesterol by an average of 15% to 18%.

When WelChol is given in combination with a statin, the combination can lower cholesterol levels more effectively than using either therapy alone. In pivotal studies where WelChol was taken with a statin, WelChol 3.8g provided up to an additional mean 16% (32 mg/dL) reduction in LDL cholesterol. WelChol is the only non-systemic cholesterol-lowering agent approved by the FDA for combination with a statin. WelChol can be used in combination with any dose of any statin.

WelChol is engineered for affinity, specificity and high capacity bile acid binding. It has been studied with four commonly prescribed statins – Lipitor[®] (atorvastatin calcium), Zocor[®] (simvastatin), Pravachol[®] (pravastatin sodium) and Mevacor[®] (lovastatin). Additionally, WelChol has been studied with fenofibrate and had no significant effect on the bioavailability of fenofibrate. Like most prescription drugs, WelChol has not been studied in combination with all medications or supplements. Patients should always tell their doctor about all medications and supplements they are taking before starting any new therapy, including WelChol.

WelChol is not for everyone, especially those with bowel blockage. Caution should be exercised when treating patients who have trouble swallowing or severe stomach or intestinal problems. Side

effects may include constipation, indigestion and gas. WelChol, either alone or in combination with a statin or fenofibrate, has not been shown to prevent heart disease or heart attacks.

WelChol is only indicated for the reduction of LDL-C either alone or in combination with a statin in patients with primary hypercholesterolemia. 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 II B), and provided additional LDL-C reductions in these patients when added to a stable fenofibrate regimen. WelChol is not indicated for use in the treatment of mixed dyslipidemia or lipid parameters other than LDL-C.

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. is the U.S. subsidiary of Japanese pharmaceutical company Daiichi Sankyo Co., Ltd. Headquartered in Parsippany, New Jersey, the company's strategic focus is on cardiovascular diseases. Research and development of new therapies is also focused in the areas of glucose metabolic disorders, infectious diseases, cancer, immunology and bone and joint diseases. Daiichi Sankyo's portfolio includes BENICAR[®] (olmesartan medoxomil) and BENICAR HCT[®] (olmesartan medoxomil/hydrochlorothiazide), the fastest growing angiotensin receptor blocker on the market, and WelChol[®] (colesevelam HCl), the number one branded bile acid sequestrant.^{6, 7} For more information, please visit www.daiichisankyo-us.com.

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¹ American Diabetes Association: Standards of medical care in diabetes – 2006. *Diabetes Care* 29(Suppl 1):S4-S42, 2006

² Grundy SM, Cleeman JI, Merz CN, Brewer HB, Jr., Clark LT, Hunninghake DB, et al. Implications of recent clinical trials for the National Cholesterol Education Program Adult Treatment Panel III guidelines. *Circulation* 110: 227-239, 2004

³ Hospital Research Associates: AHA Convention Surveys, JRA, November 2006

⁴ Ibid

⁵ Ibid

⁶ Data are representing May 2002 – February 2006 from IMS Health. National Prescription Audit, February 2006

⁷ IMS Health National Prescription Audit, September 2006

