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Colesevelam HCl Combined With Metformin or with Sulfonylurea-based Therapy Significantly Lowers Blood Glucose (A1C) in Patients with Type 2 Diabetes

Results from two studies recently presented at the American Association of Clinical Endocrinologists Annual Meeting

Parsippany, NJ (June 15, 2007) – Results from two clinical trials demonstrated that colesevelam HCl in combination with either Metformin or Sulfonylurea-based therapy in patients with inadequately-controlled type 2 diabetes, significantly reduced glucose levels versus placebo. The studies were presented via posters recently at the American Association of Clinical Endocrinologists (AACE) 16th Annual Meeting and Clinical Congress.

The first trial studied the effects of colesevelam HCl in patients with type 2 diabetes inadequately controlled on metformin-based therapy. Patients who received colesevelam HCl therapy had significant reductions in A1C (-0.54%; $p<0.001$) at week 26, with a significant treatment difference observed as early as week 6 (-0.46%; $p<0.001$). Fasting plasma glucose (-13.9 mg/dL; $p=0.014$) and fructosamine (-23.2 µmol/L; $p<0.001$) were reduced in the colesevelam HCl group by week 26 relative to placebo. Colesevelam HCl also reduced mean low-density lipoprotein cholesterol levels and hs-CRP.

"The important finding from this study is that a single drug affects two aspects of treatment that endocrinologists want to address in diabetes mellitus patients; that is to safely improve both glucose and lipid levels," said Harold E. Bays, MD, Louisville Metabolic and Atherosclerosis Research Center Inc., Louisville, KY, principal investigator of the study.

A second trial studied the effects of colesevelam HCl in patients with type 2 diabetes inadequately controlled on sulfonylurea-based therapy. Patients who received colesevelam HCl were shown to have significant reductions in A1C (-0.54%; $p<0.001$) and fasting plasma glucose (FPG) (-13.5mg/dL; p-0.009) levels vs. placebo at week 26. A significant reduction in A1C was seen as early as week 6 (-0.44%; $p<0.001$). Participants' lipid profiles in the colesevelam HCl group also showed substantial improvement over placebo.

"People with uncontrolled type 2 diabetes and high cholesterol face a number of challenges in keeping their glucose levels and cholesterol in check. This study demonstrated the potential to improve two important metabolic parameters with one drug," said Vivian

Fonseca, MD, Tulane University Health Science Center, New Orleans, LA, principal investigator of the study.

The American Diabetes Association 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]

About the Studies

The colesevelam HCl/metformin-based study was a randomized, double-blind, parallel-group, multicenter study conducted in 316 patients with type 2 diabetes mellitus (A1C 7.5%-9.5%) receiving a stable dose of metformin or metformin plus other oral anti-diabetic treatment for three months. Patients entered a 2-week, single-blind placebo run-in, after which patients were randomized to 26 weeks of colesevelam HCl 3.75 g/d (n=159) or placebo (n=157) added to their pre-study metformin-based type 2 diabetes regimen. There were no treatment-related serious adverse events.

The colesevelam HCl/sulfonylurea-based study was also a randomized, double-blind, parallel-group, multi-center study conducted in 461 patients with type 2 diabetes mellitus (A1C 7.5%-9.5%) receiving a stable dose of a sulfonylurea alone or in combination with other oral anti-diabetic regimens for three months. Patients entered a 2-week, single blind placebo run-in, after which patients were randomized to colesevelam HCl 3.75 g/d (n=230) or placebo (n=231), added to their pre-study sulfonylurea-based regimen. The primary endpoint was a change from baseline in plasma A1C at week 26.

On January 2, 2007, Daiichi Sankyo, Inc. 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.

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 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., 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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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