For more information, please contact:

KineMed
Scott Turner PhD, Vice President Research and Development
+1-510-655-6525, ext. 101

Brent Vaughan, Chief Business Officer
+1-510-655-6525, ext. 110

Daiichi Sankyo, Inc.
Kimberly Wix, Director, Public Relations
+1-973-695-8338, kwix@dsus.com

Rich Salem, Executive Director, Public Affairs
+1-973-695-8330, rsalem@dsus.com

New Discovery of Key Difference in Bile Acid Metabolism in Patients with Type 2 Diabetes May Suggest Underlying Disorder

First Extensive Report of Bile Acid Aberration in Type 2 Diabetes Patients Warrants Further Study

Emeryville, CA and Parsippany, NJ (June 9, 2008) – KineMed, Inc., and Daiichi Sankyo, Inc., announced that researchers have discovered a key difference in bile acid metabolism in people with type 2 diabetes which may suggest a newly identified underlying disorder.

It has long been known that bile acids help the body absorb fat and cholesterol. In the last decade, we learned that bile acids are important signaling molecules that regulate the metabolism of glucose, fat, and energy. And until now, there has been only preliminary data suggesting alterations in bile acid metabolism in people with type 2 diabetes. Now new data highlight crucial alterations in bile acid metabolism in this population. Researchers reported results from the first controlled study addressing this issue, which they hope will lead to a better understanding of how bile acid metabolism is impacted in people with type 2 diabetes.

The study found that the most important bile acid, cholic acid (CA), had a significantly higher synthesis rate in people with type 2 diabetes than in patients with normal glucose levels. Researchers also learned that the rate at which deoxycholic acid (DCA) was recycled back into the liver (i.e. DCA input rate) was almost twice as great in those with type 2 diabetes as in the healthy subjects. In addition, the total amount of bile acid synthesized by the liver was elevated, although not statistically significantly, in people who have type 2 diabetes as compared to the healthy control group.

KineMed, Inc., a pathway-based drug discovery and development company, initiated the research which used their proprietary translational medicine technology, KineMarker™. The results from the study were presented at the American Diabetes Association's 68th Scientific Sessions. The research was

funded with an investigator-initiated grant from Daiichi Sankyo, Inc.

"We expect that physicians and other researchers will eagerly watch as this evolves," said Elizabeth Murphy, M.D., DPhil, Chief, Endocrinology and Metabolism, San Francisco General Hospital, consultant to KineMed and lead study investigator. "We've long wanted to know the relationship between type 2 diabetes and bile acid metabolism, and the unique insights provided by KineMed's technology have now answered some of our questions. In the second phase of our study, we are investigating whether treatment with the bile acid sequestrant colesevelam HCl may improve an underlying disorder in bile acid metabolism in patients with type 2 diabetes. We're heading down a fascinating path that may lead to a new approach to fighting this disease, which strikes some 21 million people in the U.S. [1] and 246 million worldwide." [2] Colesevelam HCl is marketed in the U.S. as Welchol™.

"Daiichi Sankyo is very excited about these findings and what they might mean for diabetes research and therapy going into the future," said Sukumar Nagendran, M.D., Senior Director, Diabetes and Metabolism, Daiichi Sankyo, Inc.

"KineMed is grateful to have collaborated with Daiichi Sankyo and leveraged its insights into pathway kinetics to identify this new inflection point for the treatment of type 2 diabetes," said David Fineman, President and CEO of KineMed.

Study Details

The study investigators hypothesized that bile acid metabolism is altered in patients with type 2 diabetes which may contribute to the observed metabolic behavior, and further, that treatment with a bile acid sequestrant (BAS) might normalize these alterations. In order to test this hypothesis, as a first step, a baseline understanding of bile acid kinetics in people with type 2 diabetes needed further illumination.

The study compared the levels and metabolism of bile acids in healthy men to that of men with type 2 diabetes. Before administering any interventions, researchers recorded baseline values of bile acids in nine men with type 2 diabetes and in 12 healthy men. The men ranged in age from 42 to 56 years old and were also matched for body mass index. From study outset, those subjects with type 2 diabetes had significantly higher blood glucose levels, as measured by A1C (A1C gives a reading of the average blood glucose levels for the past two to three months). The men with type 2 diabetes also had significantly higher fasting glucose as well as triglyceride levels.

In the study, bile acid tracers were given to the men after they had eaten their evening meal. The researchers then recorded blood samples at 13, 17.5, 24, 37, 46, 63, 70 and 91 hours after the bile acid tracers were administered. No differences between the two groups were observed for cholic acid (CA) or the chenodeoxycholic acid (CDCA) pool sizes, CDCA synthesis rate, or bile acid fractional turnover rates. However, compared to the healthy cohort (HC), the men with type 2 diabetes showed a significantly higher CA synthesis rate (15.9 ± 3.1 vs. HC 9.5 ± 3.2 µmol/kg/d; $p<0.01$), DCA input rate (9.0 ± 1.5 vs. HC 4.9 ± 2.4 µmol/kg/d; $p<0.01$), DCA pool size (21.4 ± 6.5 vs. HC 13.7 ± 6.3 µmol/kg; $p<0.05$) and total

bile acid synthesis (28.1 ± 6.7 vs. HC 18.5 ± 6.4 µmol/kg; $p<0.05$). The researchers concluded that these changes in bile acid metabolism may contribute to altered glucose, fat, and energy metabolism in patients with type 2 diabetes.

About KineMarker™ Technology

KineMed's KineMarker technology is designed to quickly demonstrate, preclinically and clinically, whether compounds are "on mechanism" or are acting upon specific metabolic pathways that are the basis for particular diseases. KineMed's technology measures the kinetics of these pathways using a stable isotope labeling technique and mass isotopomer distribution analysis (MIDA), allowing observation of treatment-induced changes in patients.

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 KineMed

KineMed, Inc., is a drug discovery and development company employing its proprietary translational medicine technology (AquaTag™ and KineMarker™) to identify active drug candidates and rapidly demonstrate human proof-of-concept in selected therapeutic areas. KineMed is actively acquiring and

advancing drug candidates in indications for which it can demonstrate functional modulation of specific biological pathways that mediate disease: cardiovascular disease, metabolic disease, neurodegenerative diseases and disease of fibrosis. The company also has multiple development programs with major pharmaceutical companies, including Bayer, Merck, Organon and Roche. For further information about KineMed, please visit: http://www.kinemed.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
[1] American Diabetes Association: Diabetes Statistics. http://www.diabetes.org/diabetes-statistics/prevalence.jsp (last visited May 27, 2008)
[2] International Diabetes Federation: Facts and Figures: Did You Know? http://www.idf.org/home/index.cfm?node=37 (last visited May 27, 2008)