

Renowned Chef Launches "Franklin's Family Fixin's" Offering Adults with Type 2 Diabetes and/or High Cholesterol a Healthy 'Fix' to Traditional Family Recipes

Acclaimed chef and type 2 diabetes sufferer Franklin Becker encourages Americans to submit their favorite family recipes for a healthy makeover

September 8, 2011; Parsippany, NJ – Some of the most enjoyable family moments are spent over a meal. Whether it's a celebration, or a typical weeknight dinner, your favorite family recipe can bring loved ones together. However, if you happen to be one of the more than 12 million diagnosed with type 2 diabetes and high LDL-C or "bad" cholesterol, 1,2 you may either feel guilty indulging in your family's favorites, or deprived that you have to give up the foods you love sharing with them.

But there is good news. Your special family meals don't have to be sacrificed for a healthier diet. A simple fix with the right ingredients may make your family recipe just right without giving up the flavor - not only for an adult with type 2 diabetes and high LDL cholesterol, but for the whole family.

Today, "Franklin's Family Fixin's" is being launched to encourage adults or family members of adults with type 2 diabetes or high LDL cholesterol to submit their favorite family recipes for a healthy makeover by acclaimed chef and type 2 diabetes patient Franklin Becker. As part of the ongoing educational campaign "Two Reasons, One Recipe," all recipes chosen for a makeover will be featured on TwoReasonsOneRecipe.com, and one person will be selected to prepare their meal with Chef Franklin Becker in his restaurant's kitchen in New York City. The focus of the campaign is to help adults with type 2 diabetes or high LDL cholesterol prepare their favorite family meals while still keeping their LDL-C and/or A1C goals on track. To submit a recipe for a "Franklin's Family Fixin" and view official rules, please visit www.twoReasonsOneRecipe.com before October 15, 2011.

To view the multimedia assets associated with this release, please visit: http://www.multivu.com/players/English/46469-Two-Reasons-One-Recipe-Campaign/.

"When managing your type 2 diabetes and/or high LDL cholesterol, healthy eating habits are important. But I know first-hand that there are certain family meals that are hard to give up, like your grandmother's casserole, or your dad's special chili. And that's where I come in – I'm asking people to send me their favorite family recipe for a healthy makeover," said Franklin Becker, acclaimed Executive Chef of Abe &

Arthur's restaurant in New York City. "My goal is to show adults living with type 2 diabetes and/or high LDL cholesterol that they can enjoy their traditional family dishes without feeling guilty or deprived."

Two Reasons, One Recipe features an online educational resource, www.TwoReasonsOneRecipe.com, where adults with type 2 diabetes and/or high LDL-C can find Chef Becker's recipes, cooking and shopping tips, and helpful information about type 2 diabetes and high LDL cholesterol. In addition to new summertime recipes, another recent addition to the web site is "Franklin's Feed," where Chef Becker will provide his personal perspective on healthy living, including his favorite exercise tips.

The campaign is supported by Daiichi Sankyo, Inc., the marketer of Welchol® (colesevelam HCl). Welchol is currently the only product approved by the FDA (Food and Drug Administration), in addition to diet and exercise, to improve both glycemic control and LDL cholesterol (LDL-C or "bad" cholesterol) in adults with type 2 diabetes and high LDL cholesterol. Originally approved in 2000 for LDL-C lowering and in 2008 for A1C reduction in adults with type 2 diabetes, a once-daily formulation of Welchol, Welchol for Oral Suspension, was approved by the FDA for both these indications in 2009. Recently, in July 2011, the FDA approved the supplemental new drug application (sNDA) for Welchol for Oral Suspension to be mixed with fruit juice or diet soft drinks, offering a new option for adult patients with primary hyperlipidemia and/or type 2 diabetes. Welchol for Oral Suspension was first approved in 2009 to be mixed with water. In addition, Welchol has a pediatric indication, specifically approved to reduce LDL-C levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia. Please see Important Information about Welchol below.

The number of Americans affected by diabetes has swelled past the 25 million mark (90 to 95 percent of all individuals with diabetes are type 2)¹, and according to the American Diabetes Association (ADA), every 21 seconds another person is diagnosed.³ The ADA and the American College of Cardiology emphasize that it is critical to reduce both A1C and LDL-C levels, as more than 50 percent of adults with type 2 diabetes also have elevated LDL-C.^{2,4,5} The ADA recommends that in general, adult patients with type 2 diabetes target an A1C level of less than 7 percent, and an LDL-C goal of less than 100 mg/dL.⁶

About Franklin Becker

Born and raised in Brooklyn, New York, Chef Becker's life has always been centered on food. By the time he was 14, Becker was working in a professional kitchen. Upon graduation from college, he attended the prestigious Culinary Institute of America from which he graduated with honors. Having cooked in the past for Revlon magnate Ronald Perelman, Becker has also held the post of Executive Chef at several fine New York establishments including Local, Capitale, the Tribeca Grand and Soho Grand Hotels and Brasserie. Chef Becker is currently Executive Chef at Abe & Arthur's.

About Welchol (colesevelam HCI)

Welchol, along with diet and exercise, lowers LDL or "bad" cholesterol. It can be taken alone or with other cholesterol-lowering medications known as statins. Welchol, along with diet and exercise, also lowers blood sugar levels in adult patients with type 2 diabetes mellitus when added to other anti-diabetic medications (metformin, sulfonylureas, or insulin). Welchol was approved by the FDA to lower bad cholesterol in 2000 and to lower blood sugar levels in 2008. Welchol is available in two formulations, Welchol tablets and Welchol for Oral Suspension, which can be mixed with water, diet soft drinks or fruit juice.

Welchol should not be used to treat type 1 diabetes or diabetic ketoacidosis, and it has not been studied with all anti-diabetic medications. Welchol is not for everyone, especially those with a history of intestinal blockage, those with blood triglyceride levels of greater than 500 mg/dL, or a history of pancreatitis (inflammation of the pancreas) due to high triglyceride levels. Welchol has not been studied in children younger than 10 years of age or in premenarchal girls.

In clinical studies of adult patients with type 2 diabetes, Welchol lowered A1C, fasting blood sugar and LDL-C, important risk factors for heart disease. The most common adverse events seen in these studies were constipation, nasal pharyngitis and dyspepsia. In clinical studies of patients with elevated LDL-C, Welchol lowered LDL-C when used alone or when added to other cholesterol-lowering medications known as statins. In these studies the most common adverse events were constipation, dyspepsia and nausea. Welchol has not been shown to prevent heart disease or heart attacks.

About Daiichi Sankyo

In keeping with its vision of becoming a "Global Pharma Innovator," the Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of customers in both developed and emerging markets. While maintaining its portfolio of marketed pharmaceuticals for hypertension, hyperlipidemia, and bacterial infections, the Group is engaged in the development of treatments for thrombotic disorders and focused on the discovery of novel oncology and cardiovascular-metabolic therapies. Furthermore, the Daiichi Sankyo Group has created a "Hybrid Business Model," which will respond to market and customer diversity and optimize growth opportunities across the value chain. For more information, please visit www.daiichisankyo.com.

Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is the U.S. subsidiary of Daiichi Sankyo Company, Ltd. For more information on Daiichi Sankyo, Inc., please visit www.dsi.com.

IMPORTANT INFORMATION ABOUT WELCHOL

Indications

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 hydroxymethylglutaryl-coenzyme (HMG CoA) reductase inhibitor (statin)
- reduce LDL-C levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia, as monotherapy or in combination with a statin after failing an adequate trial of diet therapy
- improve glycemic control in adults with type 2 diabetes mellitus

Important Limitations of Use

- Welchol (colesevelam HCI) should not be used for the treatment of type 1 diabetes or for the treatment of diabetic ketoacidosis
- Welchol 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 has not been studied in children younger than 10 years of age or in premenarchal girls

Contraindications

Welchol is contraindicated in individuals with a history of bowel obstruction, those with serum triglyceride (TG) concentrations of >500 mg/dL, or with a history of hypertriglyceridemia-induced pancreatitis.

Warnings and Precautions

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, a history of 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 (cyclosporine, 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.

To avoid esophageal distress, Welchol for Oral Suspension should not be taken in its dry form.

Due to tablet size, Welchol for Oral Suspension is recommended for, but not limited to, use in the pediatric population as well as in any patient who has difficulty swallowing tablets.

Phenylketonurics: Welchol for Oral Suspension contains 48 mg phenylalanine per 3.75 gram dose.

Adverse Reactions

In clinical trials, the adverse reactions observed in ≥2% of patients, and more commonly with Welchol than placebo, regardless of investigator assessment of causality seen in:

- Adults with Primary Hyperlipidemia 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%)

- Pediatric patients with heFH primary hyperlipidemia were: nasopharyngitis (6.2% vs 4.6%), headache (3.9 vs 3.1%), fatigue (3.9% vs 1.5%), creatine phosphokinase increase (2.3% vs 0.0%), rhinitis (2.3% vs 0.0%), and vomiting (2.3% vs 1.5%)
- Adult patients with Type 2 Diabetes 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 (colesevelam HCl)
- Reduced International Normalized Ratio (INR) has been reported in patients receiving warfarin concomitantly with Welchol
- Elevated thyroid-stimulating hormone (TSH) has been reported in patients receiving thyroid hormone replacement therapy

Pregnancy

Welchol is Pregnancy Category B.

Please visit http://www.welchol.com/pdf/Welchol_Pl.pdf for full Product Information on Welchol.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For more information on Welchol, call 877-4-DSPROD (877-437-7763), or go to the Welchol website at www.Welchol.com.

For patients having difficulty affording their Welchol medication, please call the Daiichi Sankyo, Inc., Open Care Patient Assistance Program at 1-866-268-7327 for more information or visit www.dsi.com.

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References

- Center for Disease Control, National Diabetes Fact Sheet 2011. Accessible at: http://www.cdc.gov/diabetes/pubs/pdf/ndfs 2011.pdf
- 2. Cheung BMY et al. Diabetes Prevalence and Therapeutic Target Achievement in the United States, 1999 to 2006. The American Journal of Medicine. 2009;122:443-453.
- 3. American Diabetes Association. I Decide to Fight Diabetes Fact Sheet. Accessed at: http://www.diabetes.org/assets/pdfs/id-factsheet.pdf.
- 4. Brunzell JD, Davidson M, Furberg CD, et al. Lipoprotein Management in Patients with Cardiometabolic Risk: Consensus Statement from the American Diabetes Association and the American College of Cardiology Foundation. *Diabetes Care*. 2008;31(4):811-822.
- 5. Buse JB, Ginsberg HN, Bakris GL, et al. Primary Prevention of Cardiovascular Diseases in People With Diabetes Mellitus: A Scientific Statement From the American Heart Association and the American Diabetes Association. *Circulation*. 2007;115:114-126. http://circ.ahajournals.org/cgi/content/full/115/1/114. Accessed June 17, 2011.
- 6. American Diabetes Association: Standards of Medical Care in Diabetes 2010. *Diabetes Care*. 2010; 33 (Suppl 1): S11-S61