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## COMBINATION DRUG THERAPY DRASTICALLY REDUCES MULTIPLE RISK FACTORS ASSOCIATED WITH CORONARY HEART DISEASE

DALLAS – April 12, 2003 – Combining two lipid-lowering medications safely and effectively reduces multiple coronary heart disease risk factors, according to UT Southwestern Medical Center at Dallas researchers.

The researchers combined a low dose of a medication that targets low-density lipoprotein (LDL) cholesterol, or the bad cholesterol, with a second drug therapy that increases high-density lipoprotein (HDL), the good cholesterol. The study involved 20 patients with combined hyperlipidemia, which is primarily characterized by high triglycerides, high LDL cholesterol and low HDL cholesterol.

The study, reported in the April 15 issue of the *American Journal of Cardiology*, found that a specific drug combination – low-dose simvastatin (Zocor) and fenofibrate – resulted in a 52 percent reduction in triglycerides, a 23 percent increase in HDL and a 28 percent reduction in LDL.

"Drug treatment for combined hyperlipidemia presents a challenge because single drug therapy rarely corrects all of the lipoprotein abnormalities observed in this condition," said Dr. Gloria Vega, professor of clinical nutrition and the study's principal investigator. "High LDL is a well-established risk factor for coronary heart disease, and high triglycerides and low HDL worsen the risk. Successful management of this condition may require combined drug therapy."

"This study provides reasonable evidence that a low dose of a statin plus fenofibrate is a relatively safe and effective drug combination for treating LDL and several emerging risk factors for coronary heart disease. No significant side effects were observed with either the cholesterol-lowering drug alone or with co-administration of the statin and fenofibrate," said Vega.

Dr. Nilo Cater, assistant professor of internal medicine and co-author of the study, said, "The rationale for looking into the combination is that there are not only people who have

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elevations in their LDL, but they also have abnormalities in other bad cholesterol particles, such as very low-density lipoproteins (VLDL) and intermediate density lipoproteins (IDL).

"Statins are very effective in lowering LDL, but have a small effect on triglycerides and HDL. This drug combination allows us to address several lipid abnormalities in a group of patients that have persistent abnormalities in these other areas even after you treat their LDL."

Study participants were given, in three 12-week periods, either 10 milligrams per day of simvastatin and a placebo, the combination of 10 mg/d of simvastatin and 200 mg/d of fenofibrate, or a double placebo.

The nine-month study also involved patients with the metabolic syndrome, which consists of a cluster of risk factors including central obesity, high triglycerides, low HDL, high blood pressure, high blood glucose and a tendency to form blood clots.

"It is our view that the future for prevention of cardiovascular heart disease will be combined lipid-lowering therapy in patients with metabolic syndrome," said Dr. Scott Grundy, the study's senior author and director of the Center for Human Nutrition.

Other UT Southwestern researchers involved in the study were Dr. Ana-Barbara Garcia-Garcia, a postdoctoral research fellow in the Center for Human Nutrition and Shinichi Meguro, a visiting junior fellow in the Center for Human Nutrition. Researchers from Heart Health Institute in Calgary, Canada, also participated.

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