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# Press Release

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## CLEVELAND CLINIC STUDY SHOWS DRUG USED TO REDUCE ABDOMINAL FAT MAY SLOW HEART DISEASE

**Embargoed until 10:30AM CST** **April 1, 2008**, Chicago: A Cleveland Clinic-led study is reporting that an experimental drug used to reduce abdominal fat, may also slow the accumulation of plaque in coronary arteries.

The study's lead author, Steven E. Nissen, M.D., Chairman of the Department of Cardiovascular Medicine at Cleveland Clinic, will share the findings on Tuesday, Apr. 1 at the American College of Cardiology's (ACC) 57th Annual Scientific Session.

His research paper, "Strategy to Reduce Atherosclerosis Development Involving Administration of Rimonabant – The Intravascular Ultrasound Study (STRADIVARIUS)," will be simultaneously published in the *Journal of the American Medical Association,* available online at the time of presentation.

The study comprised 839 patients with coronary blockages and severe abdominal obesity in the North America, Europe, and Australia. The patients weighed an average of 228 pounds and had a waist circumference exceeding 46 inches. During the study half of the patients received Rimonabant, an investigational weight-loss drug approved in some European countries, but not the United States. The other half received a placebo for 18 months. At the end of the18 months, the rimonabant-treated patients had lost approximately 9.5 pounds and reduced their waistlines by about 1.8 inches.

The STRADIVARIUS study measured the accumulation of plaque in the arteries or atherosclerosis over time using intravascular ultrasound (IVUS), a technique that uses sound waves to create images of the walls of the arteries. For the primary measure of success, the Rimonabant-treated patients showed a reduction in plaques that did not reach statistical

significance, p = 0.22. However, the secondary IVUS endpoint did show a significant benefit, p =0.03.

“Although the study did not achieve success for the primary endpoint, the reduction in plaque volume for the secondary endpoint suggests that this treatment strategy may work to limit progression of coronary disease.” Dr. Nissen said. “This should not be considered final proof of effectiveness, but these findings warrant additional studies to gather further evidence to assess whether reducing abdominal fat can slow progression of heart disease.”

In STRADIVARIUS, patients treated with rimonabant increased their levels of HDL-C (good cholesterol) by 22.4%, reduced a type of fat known as triglycerides by 20.5%, and reduced a measure of inflammation, C-Reactive Protein by 50.3%.

Rimonabant is the first of a new generation of weight-loss drugs that block the cannabinoid receptors in the brain. Research has previously shown that blocking the cannabinoid receptor results in reduced hunger, weight loss, and favorable metabolic effects.

Rimonabant is not currently approved by the U.S. Food and Drug Administration, but has been available in Europe for over a year. In the STRADIVARIUS study, a higher rate of psychiatric side effects was documented, occurring in 43.4% of rimonabant-treated patients and 28.4% of placebo-treated patients.

**About Cleveland Clinic**

Cleveland Clinic, located in Cleveland, Ohio, is a not-for-profit multispecialty academic medical center that integrates clinical and hospital care with research and education. Cleveland Clinic was founded in 1921 by four renowned physicians with a vision of providing outstanding patient care based upon the principles of cooperation, compassion and innovation. *U.S. News & World Report* consistently names Cleveland Clinic as one of the nation’s best hospitals in its annual “America’s Best Hospitals” survey. Approximately 1,800 full-time salaried physicians and researchers at Cleveland Clinic and Cleveland Clinic Florida represent more than 100 medical specialties and subspecialties. In 2007, there were 3.5 million outpatient visits to Cleveland Clinic and 50,455 hospital admissions. Patients came for treatment from every state and from more than 80 countries. Cleveland Clinic’s Web site address is www.clevelandclinic.org.

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