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Abbott Statement on ARBITER 6 - HALTS Results and Abbott's Niaspan (niacin extended-release)

Study results released today by the American Heart Association and the New England Journal of Medicine

ORLANDO, Fla., Nov. 15, 2009 — Results from the investigator-initiated ARBITER 6 - HALTS study showed patients at high cardiovascular risk had significant regression of atherosclerosis after 8 and 14 months of therapy with Abbott's Niaspan® (niacin extended-release tablets) plus a statin, the study's primary endpoint. In a pre-specified secondary endpoint of the study, treatment with Niaspan plus statin also resulted in significantly fewer major adverse cardiac events, (or MACE, a composite endpoint consisting of heart attack, myocardial revascularization, admission to the hospital for an acute coronary syndrome, and death from coronary heart disease), as compared to ezetimibe plus a statin.

The study was stopped early after a pre-specified interim analysis was conducted on 208 patients who had completed treatment and had undergone final ultrasound imaging of the carotid artery to measure the impact of treatment on atherosclerosis. Atherosclerosis is fat build-up in the arteries and in the early stages it can be found inside the lining of the arteries, known as intima media thickness (IMT). HALTS measured IMT in the carotid artery.

"The ARBITER 6 - HALTS study is the first study showing that HDL-raising with Abbott's Niaspan on top of statin regresses atherosclerosis compared to an LDL-lowering strategy," said Eugene Sun, M.D, vice president, Global Pharmaceutical Development, Abbott. "These data reinforce the importance of looking beyond LDL treatment targets to address other lipid parameters."

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Niaspan is not indicated to promote regression of atherosclerosis in combination with a statin. In patients taking Niaspan, the most commonly reported adverse event was flushing of the skin, a transient effect associated with niacin therapy. Adverse drug effects were cited as the reason for withdrawal in three ezetimibe patients and 17 niacin patients. The difference between treatment groups was not statistically significant.

ARBITER 6 - HALTS

The ARBITER 6 - HALTS study explored treatment approaches in patients at high cardiovascular risk already taking statins to control bad LDL cholesterol. The primary endpoint of the study compared the effect on atherosclerosis of raising good HDL cholesterol with the addition of Abbott's Niaspan to a statin versus LDL-lowering with the addition of ezetimibe. There were four secondary endpoints: change in lipid values; a composite endpoint consisting of MACE; drug discontinuation due to adverse effects; and health-related quality of life. ARBITER 6 - HALTS, led by Allen Taylor, M.D., of Washington Hospital Center, was conducted and analyzed independent of Abbott. Abbott provided funding and medication to support the study.

ARBITER 6 - HALTS Study Design and Patient Population

ARBITER 6 - HALTS is a prospective, randomized, parallel group, open-label, blinded endpoint study, which means the treatment was not blinded to patients or the investigators, but the analyses of scans were blinded. The study included 362 patients with coronary heart disease or risk equivalents, LDL less than 100 mg/dL and HDL less than 50 for men or 55 mg/dL for women receiving chronic statin therapy. Baseline mean HDL in the study was 43 mg/dL and mean LDL was 82 mg/dL. At the time of the pre-specified interim analysis, the 208 patients who completed treatment and final imaging were included in the analysis.

NIASPAN Indications

NIASPAN is a prescription medication, used along with diet and exercise, to improve cholesterol levels. NIASPAN raises HDL ("good") cholesterol and lowers LDL ("bad") cholesterol and triglycerides. Niacin is also used to reduce the risk of recurrent heart attacks in patients with high cholesterol. In patients with coronary artery disease and high cholesterol, niacin, in combination with a bile acid binding resin, has been shown to slow down or reduce atherosclerosis, the hardening of coronary arteries due to plaque build-up. NIASPAN has not been shown to prevent the development of heart disease.

Important Safety Information About NIASPAN

NIASPAN is contraindicated in patients with liver problems, stomach ulcers, or serious bleeding problems; and those allergic to any product ingredient. NIASPAN is the only prescription extended-release form of niacin. Liver damage has been reported when NIASPAN has been substituted for equivalent doses of immediate-release niacin.

Patients should check with their healthcare provider before changing their medication. NIASPAN should be used with caution in patients who consume large amounts of alcohol. Blood tests may be performed before and during treatment with NIASPAN to check for liver problems. Patients treated with NIASPAN in combination with a statin should be monitored for any unusual muscle pain, tenderness, or weakness, as this could be a sign of a rare but serious side effect. Diabetic patients should be observed closely as NIASPAN may cause a dose-related increase in blood sugar levels. Flushing (warmth, redness, itching, and/or tingling of the skin) is the most common side effect. This sensation usually occurs when starting NIASPAN or during dose increases and may become less frequent over time. In most patients, flushing is mild to moderate. Some people may experience more severe and intense flushing. Additional symptoms may include rapid or pronounced heartbeat, shortness of breath, swelling, sweating, chills, dizziness, and in rare cases, fainting. NIASPAN should be used with caution in patients with a history of gout or kidney problems. Some medicines should not be taken with NIASPAN. Patients should tell their healthcare provider about all the medicines they take. Other common side effects with NIASPAN may include headache, pain, diarrhea, indigestion, nausea, vomiting, itching, and rash.

Page 4

For full prescribing information, please visit <http://www.rxabbott.com/pdf/niaspan.pdf> or www.niaspan.com.

About Abbott

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