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22.10.2010 – 18:32 Uhr

# New JUPITER Analysis Demonstrates CRESTORTM (rosuvastatin) Significantly Reduces Major Cardiovascular Events in High Risk Patients

*London (ots/PRNewswire) -*

A post-hoc-analysis from
JUPITER published in the European Heart Journal shows CRESTOR(TM) (rosuvastatin) 20 mg significantly reduced major cardiovascular (CV) events, defined as the combined end-point of CV death, stroke and myocardial infarction, compared to placebo, by 50% (p=0.028; CI 0.27-0.93) in high risk patients with a 10-year Framingham risk score >20% and by 43% in patients with an extrapolated SCORE risk greater than or equal to 5% (p=0.0003; CI 0.32-0.68). The risk reductions observed in this patient population were consistent with those seen in the primary JUPITER analysis.

This analysis is based on subgroup data from the landmark JUPITER study which studied men and women with low to normal LDL-C cholesterol levels but at increased cardiovascular risk as identified by age and elevated hsCRP.

"This newly published analysis of the JUPITER study reinforces the importance of rosuvastatin as an appropriate treatment option to reduce the risk of major cardiovascular events in high-risk patients as defined by the Framingham and SCORE risk factor assessment tools," said Michael Cressman, Executive Director of Clinical Research for CRESTOR. "Clinical studies have previously shown that rosuvastatin was the most effective statin at lowering LDL-C, had a significant effect on raising HDL-C and taken together with this analysis of JUPITER data, provides physicians with important information to help effectively reduce CV risk."

This analysis, now published in the European Heart Journal, was the basis for the approval of CRESTOR in April in 19 EU countries, for the prevention of major CV events in patients who are at high risk* of having a first cardiovascular event.

In JUPITER, rosuvastatin 20 mg was well tolerated in nearly 9,000 patients. There was no difference between treatment groups for major adverse events. There was a small increase in physician reported diabetes which is in line with data from other large placebo controlled statin trials. This finding has been reflected in the updated Summary of Product Characteristics (SmPC).

*high risk patients defined as having a SCORE greater than or equal to 5% or Framingham > 20%.

ABOUT JUPITER:

JUPITER was a long-term, randomised, double-blind, placebo-controlled, large-scale study of 17,802 patients designed to determine if rosuvastatin 20 mg decreased the risk of heart attack, stroke and other cardiovascular events in patients with low to normal LDL-C but at increased cardiovascular risk as identified by age and elevated high-sensitivity C-reactive protein (hsCRP). The majority of patients had at least one other risk factor including hypertension,

low HDL-C, family history of premature coronary heart disease (CHD) or smoking. hsCRP is a recognised marker of inflammation which is associated with an increased risk of atherosclerotic cardiovascular events. JUPITER was stopped early by the Data Safety Monitoring Board due to meeting pre-defined stopping rules for efficacy in patients treated with CRESTOR. There was a small increase in physician reported diabetes (2.8% in patients taking CRESTOR vs. 2.3% in patients taking placebo) observed in the JUPITER trial.

This new indication is based on a post-hoc analysis described in section 5.1 of the EU SmPC which reads, 'In a post-hoc analysis of a high-risk subgroup of subjects with a baseline Framingham risk score >20% (1558 subjects) there was a significant reduction in the combined end-point of cardiovascular death, stroke and myocardial infarction (p=0.028) on rosuvastatin treatment versus placebo. The absolute risk reduction in the event rate per 1000 patient-years was 8.8. Total mortality was unchanged in this high risk group (p=0.193). In a post-hoc analysis of a high-risk subgroup of subjects (9302 subjects total) with a baseline SCORE risk  greater than or equal to 5% (extrapolated to include subjects above 65 yrs) there was a significant reduction in the combined end-point of cardiovascular death, stroke and myocardial infarction (p=0.0003) on rosuvastatin treatment versus placebo. The absolute risk reduction in the event rate was 5.1 per 1000 patient-years. Total mortality was unchanged in this high risk group (p=0.076)'.

JUPITER is a part of AstraZeneca's extensive GALAXY clinical trials programme, designed to address important unanswered questions in statin research. Currently, more than 65,000 patients have been recruited from 55 countries worldwide to participate in the GALAXY Programme.

ABOUT CRESTOR (ROSUVASTATIN):

CRESTOR has now received regulatory approval in over 100 countries. More than 19 million patients have been prescribed CRESTOR worldwide. Data from clinical trials and real world use shows that the safety profile for CRESTOR is in line with other marketed statins. CRESTOR is not indicated to slow the progression of atherosclerosis within the EU. The rosuvastatin SmPC has also been updated to include an indication for the treatment of dyslipidaemia in children and adolescents with heterozygous familial hypercholesterolaemia. New statin class labeling has also been included relating to depression, sexual dysfunction, sleep disturbance, oedema, dyspnoea, cough and interstitial lung disease.

ABOUT ASTRAZENECA

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialisation of prescription medicines. As a leader in gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease medicines, AstraZeneca generated global revenues of US $32.8 billion in 2009. For more information please visit: http://www.astrazeneca.com

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