

news release

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ASTRAZENECA SUBMITS ITS NEW SUPERSTATIN, CRESTOR™, FOR REGULATORY APPROVAL IN THE US AND EUROPE

DEVELOPMENT OF VIOZAN[™] COPD TREATMENT TO BE DISCONTINUED; RESOURCES TO BE REALLOCATED TO MORE PROMISING PRODUCTS IN R&D PIPELINE

AstraZeneca announced today that the regulatory file for CrestorTM (rosuvastatin), a new statin for lipid lowering, has been submitted in the USA and Europe and that it had discontinued further development of ViozanTM, the D₂B₂ agonist for the treatment of Chronic Obstructive Pulmonary Disease (COPD).

CRESTOR™

Crestor[™] has been submitted to the Food and Drug Administration (FDA) and European authorities for the management of hypercholesterolaemia, mixed dyslipidaemia and isolated hypertriglyceridaemia.

The submissions are based on data from the clinical development programme involving over 4,000 patients including head-to-head comparative studies which demonstrate that Crestor[™] has a dramatically beneficial effect on lipid levels and can quickly get patients to the recommended US and European cholesterol guidelines. The data show that Crestor[™] is superior to three other currently available statins in lowering low density lipoprotein - LDL-C (sometimes referred to as 'bad' cholesterol) and that greater numbers of patients could reach their target cholesterol level with Crestor[™] than with other widely prescribed statins. In phase II clinical trials Crestor[™] demonstrated significant dose-dependent reductions in LDL-C of up to 65 per cent across the dose range.

Coronary heart disease (CHD) is a major cause of morbidity (health impairment) and the leading cause of death in the Western world. LDL-C is the most significant contributory risk factor to atherosclerosis, a common cause of CHD and high cholesterol levels are one of the most important risk factors in predicting CHD risk in the population. It is estimated that 65 million Americans need some type of

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intervention for high cholesterol, and of these, 36 million will need medical intervention.

The global statin market is estimated to be worth more than \$14bn and is growing at a rate of more than 20 per cent.

AstraZeneca licensed worldwide rights to Crestor[™] from Shionogi & Co Ltd, the company that discovered the drug, in April 1998 and carried out a comprehensive clinical development programme leading to submission.

VIOZAN™

AstraZeneca announced results of comparative Phase III clinical studies with Viozan[™] which confirmed the levels of safety and efficacy reported in Phase II studies but had not shown the sustained additional longer term benefits that were expected in comparison with other available therapies. As a result, the decision to discontinue Viozan[™] has been taken to allow the company to focus its resources on more promising products in AstraZeneca's rich pipeline.

Research on Viozan[™] formed part of the work on Respiratory and Inflammatory treatments at AstraZeneca's Charnwood R&D Centre, near Loughborough in the UK, where development of new treatments for respiratory diseases will continue. AstraZeneca has recently launched Symbicort[®] for asthma in Europe.

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