20 January 2011
EMA/37551/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Pravafenix

fenofibrate/pravastatin

On 20 January 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Pravafenix, fenofibrate/pravastatin, 160 mg/40 mg, hard capsule, intended the treatment of high coronary heart disease (CHD)-risk adult patients with mixed dyslipidaemia characterised by high triglycerides and low HDL-cholesterol levels whose LDL-C levels are adequately controlled while on a treatment with pravastatin 40 mg monotherapy. The applicant for this medicinal product is Laboratoires S.M.B. S.A. They may request a re-examination of the CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substances of Pravafenix are fenofibrate and pravastatin, lipid modifying agents, (ATC code: C10BA03). Pravafenix combines two compounds, which have different modes of action and show additive effects in terms of reduction of serum lipid. Pravastatin is a competitive inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase, the enzyme catalysing the early rate-limiting step in cholesterol biosynthesis. Fenofibrate is a fibric acid derivative and its lipid modifying effects are mediated *via* activation of Peroxisome Proliferator Activated Receptor type alpha (PPARα). The respective effects of pravastatin and fenofibrate are complementary. Pravastatin is more effective in reducing LDL-C and total cholesterol but presents only modest effects on TG and HDL-C while fenofibrate is more effective in decreasing TG and increasing HDL-C levels, but with few effects on LDL-C.

The benefits with Pravafenix are its ability to effectively lower lipid parameters in the subgroup of high coronary heart disease -risk adult patients with mixed dyslipidaemia defined as TG >204mg/dl and HDL-C <34mg/dL. The most common side effects are: abdominal distension, abdominal pain, abdominal pain upper, constipation, diarrhoea, dry mouth, dyspepsia, eructation, flatulence, nausea, abdominal discomfort, vomiting, and increased transaminases.

A pharmacovigilance plan for Pravafenix will be implemented as part of the marketing authorisation.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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The approved indication is: "Pravafenix is indicated for the treatment of high coronary heart disease (CHD) -risk adult patients with mixed dyslipidaemia characterised by high triglycerides and low HDL-cholesterol levels whose LDL-C levels are adequately controlled while on a treatment with pravastatin 40 mg monotherapy."

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Pravafenix and therefore recommends the granting of the marketing authorisation.