European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 27 April 2006
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION[*]
for
ACOMPLIA

International Nonproprietary Name (INN): ***rimonabant***

On 27 April 2006 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,[**] recommending to grant a marketing authorisation for the medicinal product ACOMPLIA, 20 mg, film-coated tablet, intended for the treatment of obesity. The applicant for this medicinal product is Sanofi-Aventis.

The active substance of Acomplia is rimonabant, which is a selective cannabinoid-1 receptor antagonist that inhibits the pharmacological effects of cannabinoid agonists. The endocannabinoid system is a physiological system that affects energy balance, glucose and lipid metabolism and body weight, and modulates the intake of highly palatable, sweet or fatty foods.

More than 6800 patients were included in the Phase II-III clinical studies related to weight management. Significant reductions in mean weight and waist circumference from baseline to one year for rimonabant were demonstrated in the three double-blind, placebo-controlled studies conducted in non-diabetic patients, and in one study with type 2 diabetics. Rimonabant was effective in maintaining weight loss for up to two years, and reduced the risk of weight regain. The treatment was associated with an increase in serum HDL-cholesterol and decrease in triglycerides. In the trial in type 2 diabetic patients who were overweight or obese treated with metformin or sulfonylurea an improvement in glycosylated haemoglobin (HbA1c) was observed.

The most common side effects are mood alterations with depressive symptoms, depressive disorders, anxiety, dizziness, insomnia, nausea, diarrhoea, vomiting, asthenia/ fatigue.

The approved indication is: "As an adjunct to diet and exercise for the treatment of obese patients (BMI ≥ 30 kg/m^2), or overweight patients (BMI > 27 kg/m^2) with associated risk factor(s), such as type 2 diabetes or dyslipidaemia (see section 5.1)." Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) 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 that there is a favourable benefit to risk balance for Acomplia and therefore recommends the granting of the marketing authorisation.

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[*] Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

[**] Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.eu.int http://www.emea.eu.int