European Medicines Agency
Veterinary Medicines and Inspections

London, 19 June 2009
Doc. Ref.: EMEA/CVMP/319738/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*
PALLADIA

International Non-proprietary Name (INN):
Toceranib

On 17 June 2009, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion, recommending granting of a marketing authorisation for the veterinary medicinal product Palladia, 10 mg, 15 mg and 50 mg tablets for dogs, intended for the treatment of Patniak grade II (intermediate grade) or III (high grade), recurrent, cutaneous mast cell tumours in dogs. The Applicant for this veterinary medicinal product is Pfizer Limited.

The active substance of Palladia is toceranib (as toceranib phosphate), a protein-tyrosine kinase inhibitor. Toceranib selectively inhibits the tyrosine kinase activity of several members of the split kinase receptor tyrosine kinase family, some of which are implicated in tumour growth, pathologic angiogenesis, and metastatic progression of cancer.

The benefit of Palladia is the anti-tumour effect in Palladia treated dogs as compared to placebo treated, Grade II and III mast cell tumour dog patients. Time to tumour progression is prolonged in dogs in a late stage of disease.

The most common side effects are gastrointestinal reactions (diarrhoea and vomiting).
The approved indication is: “Treatment of non-resectable Patniak grade II (intermediate grade) or III (high grade), recurrent, cutaneous mast cell tumours in dogs”.

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 CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Palladia and therefore recommends the granting of the marketing authorisation.

* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

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