European Medicines Agency
Veterinary Medicines and Inspections

London, 19 September 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*
MASIVET

International Non-proprietary Name (INN):
Masitinib mesylate

On 17 September 2008, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the veterinary medicinal product Masivet, 50 mg and 150 mg, film-coated tablets for dogs, intended for the treatment of non-resectable dog mast cell tumours (Grade 2 or 3) with confirmed mutated c-KIT tyrosine kinase receptor. The Applicant for this veterinary medicinal product is AB Science S.A..

The active substance of Masivet is masitinib (in form of masitinib mesylate), a protein-tyrosine kinase inhibitor, which showed *in vitro* selectively and effectively highest affinity for mutated forms of the c-KIT tyrosine kinase receptor.

The benefits of Masivet are a significantly longer Time-to-Tumour Progression (TTP) as compared to placebo in dogs with mast cell tumours (Grade 2 or 3) with confirmed mutated c-KIT tyrosine kinase receptor. The most common side effects are gastrointestinal reactions (diarrhoea and vomiting).

The approved indication is: "Treatment of non-resectable dog mast cell tumours (Grade 2 or 3) with confirmed mutated c-KIT tyrosine kinase receptor".

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 Masivet 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.

** Applicants may appeal any CVMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

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