16 July 2010
EMA/CVMP/177595/2010
Veterinary Medicines and Product Data Management

Committee for Medicinal Products for Veterinary Use

Post-authorisation summary of opinion*

Masivet

International non-proprietary name (INN): Masitinib

On 14 April 2010, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a negative opinion, recommending the refusal of a variation to the terms of the marketing authorisation for the veterinary medicinal product Masivet. The Marketing Authorisation Holder for this veterinary medicinal product is AB Science S.A.. The scope of the variation was a widening of the current indications to allow treatment of non-resectable dog mast cell tumours (Grade 2 or 3) independent of c-kit status.

The applicant requested a re-examination of the opinion. After considering the grounds for this request, the CVMP re-examined the opinion, and confirmed the refusal of the marketing authorisation on 13 July 2010.

The grounds for the negative opinion relate to the following points:

- Primary efficacy parameter – Time to tumour progression (TTP)
  The results in regard to TTP for dogs that remained in the study during the second study phase ("compassionate program") do not provide evidence for efficacy in carriers of wild-type c-kit. Thus the benefit-risk balance is considered to be negative for this subgroup;

- Secondary efficacy parameter – Overall survival
  The results in regard to the survival rates for the second study phase ("compassionate program") do not provide evidence for clinically relevant effects for the wild-type c-kit carriers. Thus the benefit-risk balance is considered to be negative for this subgroup;

The CVMP considered that the benefit-risk balance for Masivet is only positive in dogs with non-resectable mast cell tumours (grade 2 or 3) with confirmed mutated c-kit.

* Summaries of opinion are published without prejudice to the Commission Decision.

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