17 February 2017
EMA/CVMP/44548/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

CYTOPOINT

Common name: lokivetmab

On 16 February 2017, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product CYTOPOINT, a solution for injection, intended for the treatment of clinical manifestations of atopic dermatitis in dogs. The applicant for this veterinary medicinal product is Zoetis Belgium SA.

CYTOPOINT is an immunological veterinary medicinal product containing lokivetmab (ATCvet code QD11AH) as active substance, which is a caninised monoclonal antibody (mAb) specifically targeting canine interleukin-31.

The benefit of CYTOPOINT is its efficacy in the treatment of clinical manifestations of atopic dermatitis in dogs. CYTOPOINT has a rapid onset of action (8 hrs) and long lasting effect (28 days). CYTOPOINT is generally well tolerated at the recommended dose. In rare cases side effects include hypersensitivity-related reactions (anaphylaxis, facial oedema, urticaria) and it may induce transient or persistent anti-drug antibodies which may reduce its efficacy.

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-risk balance for CYTOPOINT and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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