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Press release

First monoclonal antibody in veterinary medicine recommended for marketing authorisation

Cytopoint treats dogs against atopic dermatitis

At its February meeting, the European Medicines Agency's (EMA) Committee for Medicinal Products for Veterinary Use (CVMP) recommended the granting of a marketing authorisation in the European Union (EU) for Cytopoint. This is a solution for injection containing the new active substance lokivetmab, the first monoclonal antibody in a veterinary medicine in the EU. It is intended for the treatment of dogs with atopic dermatitis, a common allergic skin disease.

A monoclonal antibody (mAb) is an immune protein that recognises and binds to a specific target protein. Lokivetmab is a caninised mAb developed by biotechnology that specifically targets and inhibits canine interleukin-31 (IL-31), an immune protein that plays an important role in atopic dermatitis.

In dogs with this disease, the immune system reacts inappropriately when the animal comes in contact with allergens found in the environment causing itchy skin. Once the dog's skin gets damaged by scratching and rubbing, secondary bacterial and yeast infections may develop as well.

The efficacy of this medicine was evaluated in a number of controlled laboratory and clinical studies. The data showed that treatment with Cytopoint reduced itching and the severity of skin disease in dogs receiving the medicine at the proposed dose of 1 mg/kg.

Cytopoint starts working within eight hours after administration and the effect lasts for up to 28 days. It comes in four different dosage forms (10, 20, 30 and 40 mg/ml) for administration to dogs of varying bodyweight.

The CVMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation.

Notes

1. This press release, together with all related documents, is available on the Agency's website.



2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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