EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 December 2020
EMA/631469/2020
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Solensia

Common name: frunevetmab

On 10 December 2020, 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 Solensia, solution for injection, intended for cats. The applicant for this veterinary medicinal product is Zoetis Belgium SA.

Solensia is an immunological medicinal product containing frunevetmab (ATCvet code QN02BG90) as active substance, which is a felinised monoclonal antibody (mAb) targeting nerve growth factor (NGF). The inhibition of NGF-mediated cell signalling was demonstrated to provide relief from pain associated with osteoarthritis.

The benefits of Solensia are its efficacy for the alleviation of pain associated with osteoarthritis in cats, when administered in accordance with recommendations, i.e. at a dose rate of 1 – 2.8 mg/kg body weight by the subcutaneous route at intervals of 28 days. Solensia would increase the range of available treatment possibilities for osteoarthritis in cats. The most common side effects are focal skin reactions (e.g. pruritus, dermatitis and alopecia) that occurred commonly in studies.

The full indication is: For the alleviation of pain associated with osteoarthritis in cats.

Detailed conditions for the use of this product is 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 Solensia 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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