EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 September 2020
EMA/CVMP/438128/2020
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Librela

Common name: bedinvetmab

On 9 September 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 Librela, solution for injection for the alleviation of pain associated with osteoarthritis in dogs. The applicant for this veterinary medicinal product is Zoetis Belgium SA.

Librela is an immunological veterinary medicinal product containing bedinvetmab (ATCvet code QN02BG91) as active substance, which is a canine 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 benefit of Librela is its efficacy in alleviation of pain associated with osteoarthritis in dogs. Librela will increase the range of available treatment possibilities for osteoarthritis in dogs. Administration of Librela at the recommended dose once a month resulted in clinically relevant improvements in owner assessment scores of pain severity, pain interference and life quality in dogs with mild to moderate osteoarthritis. Librela is generally well tolerated at the recommended dose; mild reactions at the injection site (e.g. swelling and heat) may uncommonly be observed.

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

Detailed conditions for the use of this product are 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 Librela 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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