22 February 2019
EMA/CVMP/131410/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

HorStem

Equine umbilical cord mesenchymal stem cells

On 21 February 2019, 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 HorStem, a stem-cell based product presented as a suspension for injection, intended for horses. The applicant for this veterinary medicinal product is EquiCord-Ymas S.L. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

HorStem is veterinary medicinal product containing equine umbilical cord mesenchymal stem cells as active substance which has immunomodulatory and anti-inflammatory properties.

The benefit of HorStem is the reduction of lameness associated with mild to moderate degenerative joint disease (osteoarthritis) in horses.

The most common side effects are acute synovitis with an acute onset of severe lameness, joint effusion and pain 24 hours after administration of the veterinary medicinal product and moderate joint effusion with no associated lameness. Complete remission follows within two weeks either without any treatment or with symptomatic treatment in severe cases.

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 HorStem 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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