



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 June 2018
EMA/CVMP/371385/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (initial authorisation)

Horse Allo 20

Allogeneic equine adipose-derived mesenchymal stem cells

On 21 June 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a negative opinion², recommending the refusal of the granting of a marketing authorisation for the veterinary medicinal product Horse Allo 20, a stem-cell based product presented as a suspension for injection.

Horse Allo 20 was proposed for the treatment of lameness associated to osteoarthritis in adult horses.

The applicant for this veterinary medicinal product is Centauri Biotech SL.

The active substance of Horse Allo 20 is allogeneic equine adipose-derived mesenchymal stem cells with potential immunomodulatory and anti-inflammatory properties that may be attributed to their paracrine activity and can possess tissue regenerative properties.

The grounds for the negative opinion relate to quality, safety and efficacy issues.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that the benefit to risk balance for Horse Allo 20 was not demonstrated to be favourable and therefore cannot recommend the granting of a marketing authorisation.

¹ Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 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.

