22 June 2018
EMA/CVMP/332343/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Arti-Cell Forte

Chondrogenic induced equine allogeneic peripheral blood-derived mesenchymal stem cells

On 21 June 2018, 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 Arti-Cell Forte suspension for injection for horses, intended for the reduction of mild to moderate recurrent lameness associated with non-septic joint inflammation in horses. The applicant for this veterinary medicinal product is Global Stem cell Technology NV. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Arti-Cell Forte is a veterinary medicinal product containing chondrogenic induced equine allogeneic peripheral blood-derived mesenchymal stem cells as the active substance. The product aims to activate chondroprotective mechanisms, such as producing extracellular matrix and influencing the inflammatory process in the joint.

The benefits of Arti-Cell Forte are its efficacy relating to the reduction of mild to moderate recurrent lameness associated with non-septic joint inflammation in horses

The most common side effects are mild increases in lameness and mild increases in temperature and swelling at the injection site in the first week after the administration

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 Arti-Cell Forte 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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