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Media and Public Relations

Press release

First stem cell-based veterinary medicine recommended for marketing authorisation

Arti-Cell Forte is indicated in horses with mild to moderate lameness due to joint inflammation

The European Medicines Agency's (EMA) Committee for Medicinal Products for Veterinary Use (CVMP) has recommended a marketing authorisation for the first veterinary stem cell-based medicine in the European Union (EU). These types of medicines have the potential to provide new treatment strategies.

Arti-Cell Forte is a veterinary medicine indicated for the reduction of mild to moderate lameness linked to joint inflammation in horses. The medicine is available as a suspension for injection and is given as a single injection into the affected joint. It contains a type of stem cell obtained from equine blood. Stem cells are cells that can develop into different types of cells. The stem cells in the medicine are treated so that they develop towards cartilage cells which can assist in repairing damaged cartilage in the joint. Arti-Cell Forte expands the range of available treatments for lameness in horses.

In a field study conducted in horses with lameness of the fetlock joint, Arti-Cell Forte showed a statistically significant improvement in the horses treated with the medicine compared with a placebo control group six weeks after treatment. The positive effect of treatment was sustained over one year. In this study a single systemic administration of a nonsteroidal anti-inflammatory drug (NSAID) was given concurrently to treatment with Arti-Cell Forte.

The most common side effects were mild increase in lameness and injection site reactions in the first week after treatment.

The applicant for Arti-Cell Forte sought scientific advice from the Agency during the development of the medicine. Scientific advice is EMA's key tool to encourage and support the development of new and innovative medicines. The CVMP opinion will now be sent to the European Commission for a decision on an EU-wide marketing authorisation.

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Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for this veterinary medicinal product is Global Stem cell Technology NV.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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