

## PRESS RELEASE



### Positive results in canine cranial cruciate ligament deficiency

- *Significant reduction of degeneration of dog cranial cruciate ligament with a single intra-articular administration of VISCO-VET*
- *Intra-articular administration of VISCO-VET is safe and well tolerated*
- *VISCO-VET MUMS/Limited Market's certification granted in Europe, reducing regulatory requirements for product development*

Jumet (Wallonia, Belgium), January 26<sup>th</sup>, 2021 - **TheraVet S.A.**, a pioneering company in the osteoarticular diseases of the companion animals, **announced today the positive results of VISCO-VET, its injectable visco-regenerating gel, in the prevention of cranial cruciate ligament (CCL) deficiency** in canine model of cranial cruciate ligament deficiency.

#### **Cranial Cruciate Ligament Deficiency: one of the main causes of disability in dogs**

CCL deficiency is one of the most important causes of stifle (knee) instability and lameness in dogs. The average prevalence of this condition, which affects 4.2 million dogs<sup>1</sup> in Europe and the United States, has been increasing steadily for several years and is now estimated at 2.6%<sup>2</sup>. It is also the main cause of secondary osteoarthritis in dogs, a painful condition significantly impacting animal's quality of life.

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<sup>1</sup> 76.8 Million dogs in USA (American Veterinary Medical Association (AVMA) U.S. pet ownership statistics, 2019) and 87.5 Million dogs in Europe (Fediaf, 2019)

<sup>2</sup> Between 0.08% and 3.77% based on several factor risk such as breed, age or sex; Witsberger TH, Villamil JA, Schultz LG, Hahn AW, Cook JL Prevalence of and risk factors for hip dysplasia and cranial cruciate ligament deficiency in dogs J Am Vet Med Assoc. 2008 Jun 15;232(12):1818-24.

CCL rupture is associated with up to a 54% increase in the risk of contralateral ligament rupture within 6 to 17 months of diagnosis<sup>3</sup>. The direct causes of CCL deficiency are little-known, but it has now been proven that inflammation in the joint plays an important role in the degeneration of the ligament and often precedes the development of joint instability, leading to ligament rupture<sup>4</sup>.

Despite this increased risk, no preventing or delaying treatment is currently available for contralateral rupture.

### **VISCO-VET: an innovative treatment that reduces and even prevents ligament degeneration**

In this context, TheraVet evaluated its visco-regenerating gel, VISCO-VET, in a placebo-controlled proof-of-concept study in a canine model of partial rupture of the CCL. This study, which included 12 dogs, evaluated over 3 months the safety and efficacy of a single injection of VISCO-VET into the animal's target joint compared to a placebo.

The macroscopic evaluation of the CCL, carried out retrospectively and blindly by a qualified veterinary surgeon, showed the presence of a vascularized healing tissue in 100% of the VISCO-VET treated ligaments, compared with only 33% in the group treated with placebo.

Additionally, animals treated with VISCO-VET showed significantly less synovialisation<sup>5</sup> of the ligament (a key sign of tissue degeneration) compared to the group treated with placebo. Given the role of degeneration in the evolution of the pathology up to the total rupture of the ligament, the histopathological changes<sup>6</sup> were evaluated by using a well-accepted semi-quantitative histological metric (Bonar score: the higher the score, the greater the degeneration).

Thus, a single intra-articular administration of VISCO-VET resulted in a statistically significant decrease ( $p < 0.001$ ) in Bonar score (by 61% as compared to placebo) and in the preservation of the microarchitecture of the ligament only in the group treated with VISCO-VET.

**These results suggest that VISCO-VET significantly reduces the degeneration processes associated with injury/partial rupture of the CCL.**

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<sup>3</sup> Chuang C, Ramaker MA, Kaur S, Csomos RA, Kroner KT, Bleedorn JA, et al. Radiographic risk factors for contralateral rupture in dogs with unilateral cranial cruciate ligament rupture. *PLoS One* 2014;9:e106389. Muir P, Schwartz Z, Malek S, Kreines A, Cabrera SY, Buote NJ, et al. Contralateral Cruciate Survival in Dogs with Unilateral Non-Contact Cranial Cruciate Ligament Rupture. *PLoS One* 2011;6:e25331.

<sup>4</sup> Hayashi K, Manley PA, Muir P. Cranial cruciate ligament pathophysiology in dogs with cruciate disease: A review. *J Am Anim Hosp Assoc* 2004; 40:385–90.

<sup>5</sup> Encapsulation of the remnants of the CCL by synovial sheath limiting the development of healing tissue bridging the gap between CCL remnants.

<sup>6</sup> Changes in (i) cell shape and number (ii) vascularization, (iii) collagen structure and (iv) ground substance

Furthermore, VISCO-VET presented an excellent safety profile. No significant side effects were reported during the 3-month observation phase following intra-articular administration.

Based on these results, VISCO-VET has been awarded by the European Medicines Agency the status of *Minor Use and Minor Species (MUMS)/Limited Market*<sup>7</sup> for the early treatment of CCL deficiency. This classification will allow TheraVet to benefit from increased support from the authorities throughout the Marketing Authorisation process and will lead to a reduction in regulatory requirements related to product development.

**Enrico Bastianelli, CEO of TheraVet, concludes:** « *We are proud of these positive results, which support the further development of VISCO-VET for the treatment of this disabling disease for which no therapeutic or preventive solution yet exists. Animal health and particularly that of small companions is an area in which there is a real need for new medical innovations. With its numerous innovative development programmes, TheraVet intends to position itself as a leading company in this sector and to offer its innovative and unique solutions to owners of fragile or sick companions as soon as possible.* »



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<sup>7</sup> A limited market is defined as a market for a veterinary medicinal product that is limited in size due to the product being indicated for a disease or condition that represents a minor use in a major species (dog being defined as a major species)

## About VISCO-VET

VISCO-VET is an injectable hyaluronan-based visco-regenerative gel supplemented. VISCO-VET is a freeze-dried product developed for local and minimally invasive treatment of osteoarticular disorders in dogs, specifically osteoarthritis and CCLD in dogs. Thanks to its unique composition, VISCO-VET displays prolonged anti-inflammatory and pro-regenerative properties locally at the site of administration.

## About TheraVet

TheraVet is a vet company created in November 2017 by Enrico Bastianelli, MD, MBA, and based in Jumet, Belgium. The Company specializes in the treatment of osteoarticular diseases in small companion animals, such as dogs, thanks to its portfolio of biological and synthetic products. TheraVet currently has two product lines: BIOCERA-VET, a line of injectable synthetic self-hardening high porosity calcium-phosphate bone substitutes and VISCO-VET, a versatile line of injectable hyaluronan-based visco-regenerative gel with anti-inflammatory and pro-regenerative properties.

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