

PRESS RELEASE



Positive results of a single intra-articular injection of VISCO-VET in canine osteoarthritis

- *Statistically significant improvement in limb function and statistically significant reduction of osteoarthritis radiological progression.*
- *Safe and well tolerated intra-articular administration of VISCO-VET with no adverse events reported over the 3-month follow-up period.*
- *European pivotal study in client-owned dogs to be launched later in 2021.*

Jumet (Wallonia, Belgium), March 4, 2021 - **TheraVet S.A.**, a pioneering company in the management of osteoarticular diseases in pets, announced today **positive results for its study evaluating VISCO-VET, its injectable visco-regenerative gel, in the prevention and treatment of osteoarthritis** in a canine model of the disease.

Canine osteoarthritis: the main joint disease in dogs

Osteoarthritis (OA) is a progressive degenerative joint disease characterized by a loss of joint cartilage and subsequent consequences on subchondral bone leading to impaired mechanical function and pain¹.

Osteoarthritis affects 20% of adult canine population² representing about 33 million dogs in Europe and in USA³ making OA the most debilitating disease in dogs. Canine OA is generally described as secondary whereby a primary abnormality such as cranial cruciate ligament

¹ Mele, E. Epidemiology of osteoarthritis. *Veterinary Focus* 17, 4–10 (2007).

² Pettitt, R. A. & German, A. J. Investigation and management of canine osteoarthritis. *In Practice* 37, 1–8 (2015).

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

rupture, incorrect bone alignments, hip and elbow disorders⁴ is present. OA develops at any age but is more commonly considered as a disease of aging with prevalence that can rise up to 80% in dogs older than 8 years⁵. Other factors such as genetics and obesity are also influencing this prevalence. The most affected sites in dogs includes stifle (i.e., knee), hip and elbow⁶.

Management of OA involves a combination of approaches including weight management, medical management and in some cases, surgical management such as arthroplasty⁶. To date, osteoarthritis is mainly medically managed using symptom-modifying drugs such as Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) or corticosteroids the objective of which is to relieve pain associated with osteoarthritis. Disease-Modifying Osteoarthritis Drugs (DMOADs) are controversial and only moderate effects have been achieved with these molecules⁷ so far.

Therefore, there is currently no available treatment associating control of pain and control of the progression of the disease.

VISCO-VET: an innovative treatment that improves function and reduces the progression of the disease

In this context, TheraVet evaluated VISCO-VET, its visco-regenerative gel, in a controlled proof-of-concept study in a canine model of induced osteoarthritis. This study, which included 16 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 single injection of hyaluronic acid (used as Control) into the animal's target joint.

The function of the affected stifle joint was objectively evaluated using a pressure walkaway system (GaitRite[®])⁸. Other pressure variables, such as limbs pressures distribution and the off-loading of affected limb (i.e., lameness), were respectively evaluated using the percentage of Total Index Pressure (%TPI)⁹ and the Gait4 dog[®] Lameness Score (GLS). Analysis of %TPI change as compared to baseline showed a statistically significant improvement at 2 ($p<0.05$) and at 3 months ($p<0.01$) after VISCO-VET single administration as compared to no significant improvement in Control. %TPI was improved by 47% and 49% respectively at 2 and 3 months in VISCO-VET group as compared to Control. Similar observation was done with GLS with

⁴ Mele, E. *Epidemiology of osteoarthritis. Veterinary Focus* 17, 4–10 (2007).

⁵ Johnston, S. A. *Osteoarthritis - joint anatomy, physiology, and pathobiology. Veterinary Clinics of North America-Small Animal Practice* 27, 699–723 (1997).

⁶ Pettiit, R. A. & German, A. J. *Investigation and management of canine osteoarthritis. In Practice* 37, 1–8 (2015).

⁷ Sandersolh, R. O., Beata, C., Flipo, R.-M., Genevois, J.-P., Macias, C., Tacke, S. Innes, J. F. (2009). *Systematic review of the management of canine osteoarthritis. Veterinary Record*, 164(14), 418–424.

⁸ Viguier, E., Le Quang, T., Maitre, P., Gaudin, A., Rawling, M., & Hass, D. (2007). *The validity and reliability of the GAITRite[®] system's measurement of the walking dog. Computer Methods in Biomechanics and Biomedical Engineering*, 10(sup1), 113–114.

⁹ %Total Index Pressure (%TPI) is defined as the sum of peak pressure recorded for the affected paw expressed as percentage of the 4 limbs

statistically significant improvement at 2 ($p<0.05$) and at 3 months ($p<0.05$) in VISCO-VET group as compared to Control.

Radiological progression of osteoarthritis was carried out by a qualified and independent veterinary radiologist by using a radiological mapping assessing the appearance of osteophytes and sclerosis (“osteophytes score”) on 15 defined locations of stifle joint¹⁰. A statistically significant reduction of osteophytes score was observed as soon as at 1 month of follow-up ($p<0.05$) and was maintained at 2 ($p<0.01$) and 3 ($p<0.05$) months of follow-up in VISCO-VET group as compared to Control. Furthermore, the effects of VISCO-VET were even more important (and significant) in the most severely affected areas of the stifles (proximal trochlear ridge or intercondylar notch).

Finally, macroscopic evaluation of the joint carried out blindly according to OARSI scoring by a qualified specialist showed a statistically significant reduction of the severity and size of cartilage damage ($p<0.05$) in central zone of lateral femoral condyle in VISCO-VET group as compared to Control.

These results suggest that a single administration of VISCO-VET significantly improves limb function and significantly reduces the progression of osteoarthritis.

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

To confirm these promising results, TheraVet is currently evaluating VISCO-VET in a Proof-of-Concept study in client-owned dogs suffering from osteoarthritis, in collaboration with Pr. Balligand of the Veterinary Faculty of Liège University (Belgium). This Proof-of-Concept study will be followed by a European pivotal placebo-controlled randomized multicentric study in client-owned dogs to be launched later in 2021.

Enrico Bastianelli, CEO of TheraVet, concludes: « *We are proud of these promising efficacy and safety results of VISCO-VET in canine osteoarthritis that confirm the potential of this innovative product for the treatment of joint diseases. Following this study, VISCO-VET is in a perfect position to open the way to a new generation of disease-modifying drugs, with long-lasting effects that, when available on the market, will bring real added value to the management and the treatment of canine osteoarthritis, a severe disease for which no real efficient treatment exists yet.* »

¹⁰ Wessely, M., Schnabl-Feichter, E. and Brühnschwein, A., (2017). Evaluation of Intra- and Inter-observer Measurement Variability of a Radiographic Stifle Osteoarthritis Scoring System in Dogs. *Veterinary and Comparative Orthopaedics and Traumatology*, 30(06), 377–384.



About VISCO-VET

VISCO-VET is an injectable hyaluronan-based visco-regenerative gel. 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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