



TheraVet completes first regulatory milestones for the US registration (NADA) of VISCO-VET in canine osteoarthritis

Jumet (Wallonia, Belgium) & College Station (Texas, USA), June 15, 2020
TheraVet S.A., the specialist of the osteo-articular diseases in small companion animals, **announces today passing the first regulatory milestones for its product VISCO-VET in the indication of canine osteoarthritis with the U.S. Food & Drug Administration's (FDA) Center for Veterinary Medicine (CVM).**

Since its creation in 2019, TheraVet USA has successfully completed the regulatory milestones required by the U.S. FDA Center for Veterinary Medicine to launch the New Drug Application (NADA) pathway for VISCO-VET, a new generation hyaluronan-based visco-analgesic, aiming to reduce pain and improve lameness associated with osteoarthritis in dogs.

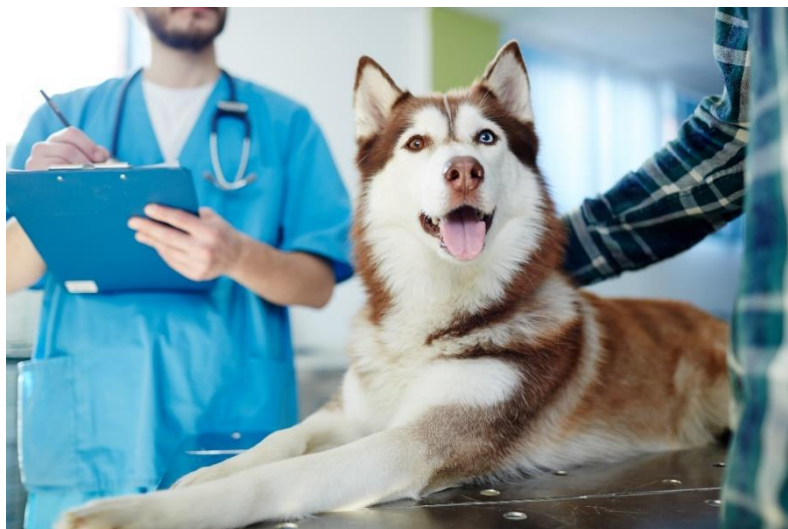
First, in November 2019, TheraVet USA has been granted the “Barrier to Innovation” fee waiver, which waives the fees paid by a sponsor to communicate, meet and receive feedbacks and approvals from the FDA under an Investigational New Animal Drug (INAD) application. This decision was supported on the ground of the innovative and medical breakthrough potential of VISCO-VET in the small companion animals’ osteoarthritis field. Following the waiver approval, TheraVet has been able to open, as early as November, VISCO-VET INAD application, and therefore to advance the regulatory dossier for the product. Finally, early March, TheraVet was awarded the exclusive CVM Veterinary Innovation program (VIP), implemented recently by CVM, and which supports and accelerates eligible sponsors’ regulatory pathway for drug approval. Since January 2020, and thanks to these achievements, TheraVet has started working closely with the FDA and is regularly meeting with CVM on VISCO-VET’ New Animal Drug Application (NADA).



The next milestone will be coordinating the launch of the clinical trial for VISCO-VET in canine osteoarthritis, in accordance with the FDA's Center for Veterinary Medicine standards. Current treatments for osteoarthritis in dogs are either limited to pain management (NSAIDs, corticosteroids), without treating the disease itself, or are very invasive (surgery). The aim of this study will be to confirm that VISCO-VET offers a safe and efficacious solution for dogs suffering from osteoarthritis.

This multicentric clinical study, currently in preparation, will be conducted with private and university veterinary practices, among which Texas A&M university and Dr. Brian Saunders, Associate Professor Orthopedic Surgery, Texas A&M University, who commented:

“We are excited to partner with the TheraVet team to evaluate the safety and efficacy of VISCO-VET in dogs suffering from osteoarthritis. The TheraVet team has been working for many years to generate an impressive amount of pre-clinical safety and proof of concept data. They are working hand-in-hand with the U.S. Food & Drug Administration's (FDA) Center for Veterinary Medicine on regulatory processes and to develop an FDA-approved multi-center clinical trial study protocol. Although we have many effective surgical treatments for osteoarthritis, not all dogs are candidates for surgery and some pet-owners are not ready for surgery for their pets. We look forward to initiating this trial, as this group of patients would benefit from a safe and effective local treatment for such a debilitating disease.”



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, using a portfolio of biological and synthetic products. TheraVet currently has two product lines in its pipeline: BIOCERA-VET, a line of synthetic injectable self-hardening high porosity calcium-phosphate bone void fillers and VISCO-VET, a versatile line of hyaluronan-based visco-antalgics with anti-inflammatory and pro-regenerative properties.

About VISCO-VET

VISCO-VET is a hyaluronan based visco-antalgic complemented with an anti-inflammatory molecule. VISCO-VET is a freeze-dried product developed for local and minimally invasive treatment of osteo-articular disorders in dogs. Thanks to its unique composition, VISCO-VET is a viscous injectable solution with spontaneous gelification properties allowing a prolonged residency and effect of active components in the affected joint. VISCO-VET targets osteo-articular diseases as osteoarthritis and cranial cruciate ligament deficiency in dogs.

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