VETBIOLIX
NEW ROUTE TO ANIMAL HEALTH

Press Release

Vetbiolix communicates interim positive results from the proof-of-concept clinical study of its drug candidate VBX-2000 (piclidenoson; A3R agonist) in dogs suffering from osteoarthritis

- **The primary objective of the study has already been achieved. A progressive, dose-dependent improvement in the mobility score (LOAD questionnaire) is observed. At the highest dose tested (500 µg/kg twice daily), this effect on mobility is clinically and statistically significant after 60 days and 90 days of treatment.**
- **At the same time, a progressive and dose-dependent reduction in the pain score (Visual Analogue Scale; VAS) is obtained. At a dose of 500 µg/kg twice a day ("bid"), the reduction is statistically significant from 60 days of treatment and until the end of the 90-day treatment period.**
- **At a dose of 500 µg/kg bid after 90 days of treatment, the beneficial effect of repeated administration of VBX-2000 on arthritic pain is confirmed on the NRS2 pain score.**

Lille, July 01st 2024 - Vetbiolix, a veterinary biotechnology company based in France dedicated to the clinical development of First-in-Class drug candidates for the treatment of periodontitis, osteoarthritis and gastric motility disorders in dogs and cats, reports first interim results of the proof-of-concept clinical study of its drug candidate VBX-2000, the first agonist of the adenosine A3 receptor (A3R), for the treatment of osteoarthritis in dogs.

The proof-of-concept clinical study VBX2400-CL-1001 POC study is an open-label, multicenter study (France, Belgium) seeking to evaluate the safety of use and the effects of repeated oral administration of VBX-2000 for 90 days on the mobility and pain of 20 dog patients suffering from osteoarthritis. At inclusion, patients are divided into two groups (objective of 10 patients per group). Group 1 is treated with VBX-2000 at a daily dose of 100 µg/kg bid orally for 90 days. Group 2 is treated with VBX-2000 at a daily dose of 500 µg/kg bid orally for 90 days. The primary objective of the study is to investigate the effects of VBX-2000 on a clinically validated mobility score: the LOAD (Liverpool-OsteoArthritis-in-Dogs questionnaire), after 90 days of treatment. The secondary objectives of the study relate to the evolution after 90 days of treatment of VAS (Visual Analog Scale) pain scores and NRS (Numerical Rating Score) scores measured by the veterinarian: NRS1 (lameness score), NRS2 (pain score). This interim analysis includes the first 15 dogs included: N=6 in group 1 and N=9 in group 2.

In both groups, repeated administration of VBX-2000 was well tolerated.

The main results are presented in the following table:

		Screenig	Inclusion Jour 0	Day 30	Day 60	Day 90	P value[$] D90 vs D0
Group 1 : 100 µg/kg bid	N	6	6	6	6	6	
	LOAD Score	21.0±7.8	25.7±8.6	19.2±8.4*	21.0±9.6	21.5±11.3	NS
	VAS score	3.5±1.9	3.8±1.9	3.4±2.6	3.1±2.1	3.1±1.9	NS
Group 2 : 500 µg/kg bid	N (patients)	9	9	9	9	9	
	LOAD score	21.4±6.8	22.9±7.2	15.7±8.1	15.4±10.0**	14.9±10.7**	P=0.008
	VAS score	4.0±2.2	4.7±2.3	3.1±1.9	2.5±1.7**	2.3±1.9**	P=0.008

[$] p value J90 vs inclusion visit by « Wilcoxon matched-pairs signed rank test ». ns: p>0.05

**p<0,05 ; **p<0.01 vs inclusion visit by « Dunn's multiple comparisons test »*

In group 1, the dose of 100 µg/kg bid for 90 days had no significant effect on the mobility score (LOAD) and the pain score (VAS). Conversely, the primary efficacy endpoint is achieved at a dose of 500 µg/kg bid. After 90 days of treatment, mobility was significantly improved (p=0.008). This improvement in LOAD was detectable from the first visit on day-30 and became statistically significant on Day-60 and Day-90. At the same time, at the dose of 500 µg/kg, a progressive reduction in the VAS pain score was observed throughout the treatment period (p=0.008 on Day-90).

In both groups, the proportion of patients with a low lameness score (NRS1) increased after 90 days of treatment compared to the proportion before treatment. However, these increases remained non-significant (p>0.05). Likewise, the proportion of patients with a low pain score (NRS2) increased in both groups. This difference compared to the proportion before treatment was statistically significant in the 500 µg/kg bid group (p<0.05).

Rémy Hanf, founder and Chief Scientific Officer of VETBIOLIX – Board member of VETBIOLIX indicates: "*The results of this interim analysis of the proof of concept study of our adenosine-A3 receptor agonist drug candidate in dogs suffering from osteoarthritis are extremely exciting. They provide the first proof of clinical effectiveness of a new therapeutic class for better management of osteoarthritis in dogs. Given the clinically significant effects obtained on both mobility and arthritic pain at a dose of 500 µg/kg bid, and without waiting for the full results of the study, we anticipate the implementation of a randomized trial versus placebo, double-blind study in dogs suffering from osteoarthritis at the beginning of 2025.*"

Matthieu Dubruque, founder and Managing Director of VETBIOLIX indicates: "*These clinical results were eagerly awaited. Due to its very innovative mechanism of action, our molecule targets the cause of osteoarthritis (degradation of cartilage) and its inflammatory consequences. VBX-2000 thus responds to a still unmet medical need, complementing the existing veterinary therapeutic arsenal. This is a new major industrial milestone reached by the company, after our successes already obtained in periodontal disease last April with VBX-1000. For these two products, we are now turning to regulatory clinical development (EMA-FDA) for the potential marketing of VBX-1000 and VBX-2000 by 2028*."

Matthieu Roquette, founder and President of VETBIOLIX indicates: " *With the positive results of this Proof of Concept clinical study, we are pleased to have respected our commitments made to our partner Can-Fite Biopharma, our investors and the veterinarian community. The global market for veterinary drugs treating osteoarthritis targeted by VBX-2000 is estimated at more than $3 billion annually. Finally, the company, with this new success, now has 2 drug candidates (VBX-1000 and VBX-2000) with high potential having demonstrated their safety of use and proof of clinical effectiveness in 2 major veterinary indications.* »

About Vetbiolix – https://www.vetbiolix.com

VETBIOLIX develops innovative products for the treatment and prevention of diseases affecting pets. VETBIOLIX has built a unique pipeline of *First-in-class* small molecules in-licensed (*exclusive and worldwide license*) from Human Biotech worldwide which will answer to veterinary unmet medical needs in periodontitis, osteoarthritis and gut motility disorders. VETBIOLIX focuses exclusively on clinical developments of its drug candidates: the company invests on (i) clinical proof of concept studies, (ii) CMC-Pharmaceutical developments, (iii) regulatory *Pilot* clinical studies and (iv) regulatory *Pivotal* clinical studies. Revenue generation of the company will be based on out-licensing and/or co-developments deals with the Veterinary Pharmaceutical Industry.

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