

Press Release

Vetbiolix activates the option on the license for RQ-10 (VBX-3000), a 5-HT₄ agonist discovered by RaQualia Pharma, to develop pet pharmaceuticals for the treatment of gut motility disorders in dogs and cats

Nagoya and Loos, December 18th, 2024 – In accordance with the provisions of the Option and License Agreement signed on April 6th, 2023 by and between RaQualia Pharma Inc. (Headquarters: Nagoya, Aichi, Japan; President & CEO: Hirobumi Takeuchi; “RaQualia Pharma”) and Vetbiolix SAS (Headquarters: Loos, Nord, France; Founder & President: Matthieu Roquette; “Vetbiolix”), Vetbiolix confirms its will to activate the Option on the License for the Product known as RQ-00000010 (“RQ-10”), a 5-HT₄ agonist discovered by RaQualia Pharma, to develop pet pharmaceuticals for the treatment of gut motility disorders in dogs and cats.

Under the terms of the Agreement, Vetbiolix is now granted with an exclusive, worldwide, and sublicensable license to develop, manufacture and market veterinary medicines containing RQ-10. Upon exercise of the exclusive option, Vetbiolix will pay option fees to RaQualia Pharma, and Vetbiolix will be responsible for future global development. RaQualia Pharma is also eligible to receive milestone payments based on development progress. In addition, if the pet pharmaceuticals containing RQ-10 are successfully marketed, Vetbiolix will pay RaQualia Pharma the sales royalty based on the product sales or license income received by Vetbiolix.

The pharmaceutical market of gastrointestinal dysmotility disorders in companion animals is estimated to be \$350 Million in 2023 and is expected to grow to 600 Million by 2031 (Coherent Market Insights). Vetbiolix models that RQ-10 (VBX-3000) has the potential to capture up to 15 to 25% of this opportunity, with peak worldwide sales of \$125 Million by 2031.

5-HT₄ receptor is a cell membrane protein that is activated by the neurotransmitter serotonin. It is expressed in various organs and in particular in the digestive system. At the gastrointestinal level, activation of 5-HT₄ receptor promotes motility by regulating contractile activity of the stomach and intestines, helping digestion and absorption. On a mechanistic point of view, activation of 5-HT₄ receptors by agonists like RQ-10 stimulates the release of another neurotransmitter, acetylcholine, which promotes smooth muscle contraction in the gastrointestinal wall. As a result, stimulation of 5-HT₄ receptors by a selective agonist like RQ-10 is a promising approach for treating various gastrointestinal

dysmotility disorders frequently encountered in dogs and cats. Notably, RQ-10 might become a first line therapy for disorders associated with delayed gastric emptying like gastroparesis in dog or chronic constipation in cat.

RQ-10 is a potent, highly selective, and orally bioavailable small molecule 5-HT₄ agonist. RaQualia Pharma has conducted various pharmacological and tolerance studies in various animal species including dog and a phase I clinical study in human supporting a high efficacy to safety ratio for RQ-10 in the treatment of dysmotility disorders in dog and cat.

Hirobumi Takeuchi, President & CEO of RaQualia Pharma, stated: *“We are delighted to announce that Vetbiolix has made the decision to exercise its full license option for RQ-10 (VBX-3000). In non-clinical studies conducted by our company in dogs, RQ-10 (VBX-3000) demonstrated a favorable pharmacokinetic and safety profile, effectively enhancing gastrointestinal and colonic motility at low doses and outperforming existing treatments. We strongly hope that the RQ-10 (VBX-3000) will greatly improve the lives of dogs and cats suffering from intestinal motility disorders, and that they will be able to spend healthy and happy lives with their owners.”*

Matthieu Roquette, Founder & President of Vetbiolix, stated: *“There is a crucial unmet medical need in pets gastrointestinal (“GI”) disorders whereas demands from the veterinary community and the pets parents are dramatically growing. We believe RQ-10 (VBX-3000) has the potential to become a “game changer” in the GI-Pet Market. Considering this, we decided to exercise the option for a full license to develop and commercialize RQ-10 (VBX-3000) for veterinary use signed with RaQualia Pharma, and thus protect Vetbiolix operating rights for RQ-10 (VBX-3000) in veterinary health. Vetbiolix is currently running two open-label, multicenter Proof-of-Concept clinical studies (“POC clinical studies”) seeking to evaluate the safety of use and the effects of repeated oral administration of RQ-10 (VBX-3000) for a couple of weeks period in owned-dogs and cats with gut motility disorders: we are expecting final clinical results of the POC clinical studies by Q2-2025 and launch of Pilot regulatory clinical studies by 2026.”*

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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About RaQualia Pharma – <https://www.raqualia.com/en/index.html>

RaQualia Pharma's mission is "We brighten people's lives through the power of innovation." RaQualia Pharma strives to deliver new medications to those suffering from diseases where no effective treatment options exist or existing treatment methods are insufficient. Guided by this philosophy, RaQualia Pharma is dedicated to the research and development of new medications not only within its own company but also through establishing a next generation drug discovery value chain by strengthening partnerships with academia, start-ups, and venture companies. RaQualia Pharma, as professionals in drug discovery, is focusing on research and development efforts with a primary focus on patients. RaQualia Pharma pursues its science to create innovative, first-in-class therapeutic medications.

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