RaQualia Pharma Inc.



Notice on Approval to Initiate Phase 1 Clinical Trial of a Novel TRPM8 Blocker in Australia

Nagoya, Japan, March 11, 2024 – RaQualia Pharma Inc. ("RaQualia") is pleased to annnouce that its licensee, Xgene Pharmaceutical Co. Ltd. (Headquartered in Hong Kong, CEO: Dr. Gene Hsu, "Xgene"), uncovered today that Xgene Pharmaceutical Pty Ltd, a subsidiary of Xgene, has received an HREC's approval to initiate a phase 1 clinical trial in Australia for a novel TRPM8 blocker (compound code: RQ-00434739/XG2002, "Compound"), which RaQualia licensed to Xgene.

The Compound, a selective TRPM8 blocker, has shown compelling pain suppression effects in multiple animal pain disease models, demonstrating clean safety profile in preclinical studies conducted by Xgene. The Compound holds great potential to be an effective treatment for a variety of acute and chronic pain disorders, including neuropathic pain such as migraine, diabetic neuropathy, etc.

This phase 1 dose-ascending trial will assess the tolerability and pharmacokinetic profile of the Compound in healthy volunteers, providing crucial data for subsequent clinical trials.

Under the license agreement with Xgene, RaQualia is entitled to receive milestone payments based on the development progress and royalties based on product sales after the product is launched. As a result of the approval to initiate the phase 1 trial, RaQualai will receive a milestone payment from Xgene, which will be recorded as business revenue for the first quarter of the fiscal year ending December 31, 2024. The impact on the Company's consolidated financial results for the current fiscal year has already been incorporated into the Company's consolidated financial forecast for the fiscal year ending December 31, 2024, which was disclosed in the Company's financial results for the fiscal year ended December 31, 2023, on February 14, 2024.

RaQualia will continue to collaborate with Xgene to further contribute to the improve the quality of life of patients suffering from pain by providing new therapeutic options for pain treatment, thereby increasing its corporate value.

For more information, please visit the Xgene's website at: https://xgenepharm.com/news/.

About Xgene

Xgene Pharmaceutical Co. Ltd. and Xgene Pharmaceutical Pty Ltd. are subsidiaries of Xgene Pharmaceutical Inc. (Headquartered in Cayman Islands, CEO: Dr. Gene Hsu). Since its founding in 2015, Xgene Pharmaceutical Inc. has been committed to developing breakthrough therapeutics to address unmet needs in neurological disease area. Xgene's proprietary link technology enables the creation of novel, multimodal, conjugated molecules for the treatment of pain and other neurological disorders. Current programs are focused on improving the efficacy and tolerability of pain therapeutics with a pipeline comprising late-stage clinical programs as well as assets in discovery and preclinical development.

For more information, please visit the company's website at https://xgenepharm.com.