

May 7, 2026

To Whom It May Concern

Notice Regarding the Initiation of a Confirmatory Study for  
"KRP-DT123," a Digital Therapeutic for Tinnitus

KYORIN Pharmaceutical Co., Ltd. (Headquarters: Chiyoda-ku, Tokyo, President and CEO: Yutaka Ogihara, "KYORIN") and SUSMED Inc. (Headquarters: Chuo-ku, Tokyo, President and CEO: Taro Ueno, "SUSMED") announced today the initiation of a confirmatory study for KRP-DT123/SMD403, a digital therapeutic designed for the treatment of tinnitus.

KRP-DT123/SMD403 is a digital therapeutic (medical device program) aiming for health insurance coverage, which is being jointly developed by KYORIN and SUSMED.

This confirmatory study (pivotal study) is a multicenter, randomized, double-blind, controlled trial to evaluate the efficacy and safety of using this application for 16 weeks in patients with distressing chronic tinnitus. Following the completion of the trial, KYORIN plans to submit an application for manufacturing and marketing approval in Japan. Currently, there are no approved digital therapeutics specifically targeting tinnitus.

KYORIN and SUSMED are conducting the development by leveraging KYORIN's knowledge in disease areas and clinical development, along with SUSMED's digital therapeutics development platform, clinical trial management system (SUSMED SourceDataSync®), and its know-how.

By developing and commercializing this application, we aim to provide a new treatment option for patients suffering from tinnitus.

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[Reference]

■About tinnitus

Tinnitus is defined as an abnormal auditory sensation perceived in the absence of an external sound source. It is estimated that the prevalence rate is 15–20% of the population, with 2–3% of the population suffering from clinically significant tinnitus<sup>1</sup>.

Pharmacotherapy is generally the most commonly chosen treatment for tinnitus, but it has been reported that the physician satisfaction with this treatment is the lowest of all current treatments in Japan<sup>2</sup>. Meanwhile, non-pharmacotherapies are currently difficult to disseminate due to issues such as the time and effort required, and lack of specific reimbursement.

1: Clinical Practice Guidelines for Diagnosis and Management of Tinnitus, Japan Audiological Society

2: Yuichi Yageta, Takashi Yoshida, Koichiro Wasano: Web-based questionnaire survey of medical treatment for tinnitus in Japan. *Audiology Japan* 67:548-557, 2024

■About KYORIN

KYORIN operates under the corporate philosophy, "KYORIN continues to fulfil its mission of cherishing life and benefiting society by contributing to better health." Based on this principle, we aim to continuously provide high-value new drugs that meet medical needs, striving to become a company that contributes broadly to people's health. In drug discovery, we focus our research efforts on the therapeutic areas of pain and autoimmune disorders and neuromuscular disease, working to create innovative new drugs that meet significant medical needs. In sales, we implement a Franchise Customer (FC) strategy, concentrating our resources on specialized areas, respiratory, otolaryngology, and urology.

<https://www.kyorin-pharm.co.jp/en/>

■About SUSMED

SUSMED is a research and development company that promotes digital medicine, and is working on the development of several DTx for insomnia and other disorders. In addition, the company have various patents such as medical applications of blockchain technology that leads to efficient clinical trials or mobile apps' technologies that makes DTx development more efficient and reliable.

URL <https://www.susmed.co.jp/en/>

Note: The information regarding the digital therapeutic (SaMD, Software as a Medical Device) contained in this press release is disclosed solely for the purpose of providing corporate information about KYORIN and SUSMED. It is not intended for the promotion or advertising of the said digital therapeutic (SaMD).