



October 16, 2025

To whom it may concern

KYORIN Pharmaceutical Co., Ltd.
TOKAI UNIVERSITY
SASMED Inc.

Announcement of Presentation in Academic Conference Regarding Result of Specified Clinical Trial using Digital Therapeutics for Tinnitus

The results of the Specified Clinical Trial (jRCTs032230359), which utilized the digital therapeutics for patients of tinnitus "KRP-DT123/SMD403" (hereinafter, "the DTx") and was conducted by Tokai University Hospital (Isehara city, Kanagawa), were reported by the Principal Investigator, Professor Koichiro Wasano (Department of Otorhinolaryngology, Head and Neck Surgery, Tokai University School of Medicine) at the "The 70th Congress of Japan Audiological Society".

The DTx was developed by KYORIN Pharmaceutical Co., Ltd. (Headquarters: Chiyoda-ku, Tokyo, President and CEO: Yutaka Ogihara) and SUSMED, Inc. (Headquarters: Chuo-ku, Tokyo; Representative Director: Taro Ueno) in the collaboration agreement¹. KYORIN cooperated with Tokai University, which implemented this specified clinical research using the DTx.

This research was a multi-center, randomized, double-blind, sham-controlled study aimed at exploratorily investigating the efficacy and safety of the DTx for patients with chronic tinnitus.

The primary endpoint, the change in the total score of the Tinnitus Handicap Inventory (THI) from week 0 to week 16 after the DTx prescription, showed a statistically significant improvement in the treatment group compared to the sham group (Δ THI -16.8 vs 3.6, $p < 0.001$). The effect was maintained 8 weeks after the end of the treatment period.

Furthermore, secondary endpoints also showed significant improvements: the change in the Tinnitus Functional Index (TFI) score showed a significant improvement ($p < 0.001$), and the Numerical Rating Scale (NRS) for tinnitus annoyance and tinnitus control both showed statistically significant improvements ($p < 0.001$ for each). Additionally, significant improvements in scores related to anxiety and insomnia (HADS Anxiety score $p = 0.017$, Athens Insomnia Scale (AIS) $p = 0.027$), and an improvement trend in depression were also observed (HADS Depression score $p = 0.082$).

No safety issues were confirmed in the treatment group.

The details of this study are currently being submitted for publication in a journal and are going to be registered and disclosed on jRCT (Japan Registry of Clinical Trials) in the future.

About tinnitus

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 Japan². Meanwhile, non-pharmacotherapies are currently difficult to disseminate due to issues such as the time and effort required, and lack of specific reimbursement.

KYORIN and SUSMED aim to solve these issues by providing new treatment options.

About Specified Clinical trials

"Clinical trials" is defined in the Clinical Trials Act (Article 2) as research to clarify the efficacy or safety of pharmaceuticals by the use of such pharmaceuticals and medical devices, etc., in humans. "Specified clinical trials" as used refers to clinical research that is funded by the manufacturers of the pharmaceuticals or medical devices or their special related parties, or clinical research on unapproved or off-label pharmaceuticals, medical devices, etc.

About sham

A DTx/app that corresponds to a placebo in pharmaceutical development.

1: Press release dated November 9, 2022 "KYORIN and SUSMED conclude Collaboration Research and Sales Agreement for development of Digital Therapeutics in Otolaryngology Field"

<https://www.kyorin-pharm.co.jp/news/2022/001680.shtml>

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