

August 28, 2024

Sawai Group Holdings Co., Ltd.

**Sawai and CureApp Conclude Japan's First*¹ Marketing License Agreement
for an Alcohol Reduction Therapeutic App**

Osaka, Japan – August 28, 2024 – Sawai Group Holdings Co., Ltd. (Sawai Group, Head office: Osaka, Japan, President: Mitsuo Sawai) announced the conclusion of a marketing license agreement with CureApp Inc. (CureApp, Head Office: Tokyo, Japan, President: Kohta Satake) for a therapeutic app for reducing alcohol intake (“the App”).

Under the agreement, Sawai Group will have exclusive marketing rights for the App, which is for treating alcohol dependence, in Japan. Cure App will be responsible for development of the App, while Sawai Group will pay CureApp a total of up to 4.8 billion yen as milestone payments comprising compensation for the marketing license and the sale amount based on the agreement, as well as royalty payments on sales once the App is launched onto the market. Also, after market launch, it is planned that healthcare institutions will introduce the App and provide treatment to patients through App Prescription System (APS), a distribution platform for therapeutic apps developed and provided by CureApp. CureApp has completed clinical trials of the App (Phase III clinical trial in Japan) which began in February 2023, clearing all primary evaluation items, and it submitted an application for manufacturing and marketing approval in March 2024. At present, there are no therapeutic app for reducing alcohol intake that have received regulatory approval as a medical device or insurance coverage in Japan*¹.

*1. Based on an investigation by CureApp. Timing of investigation: August 2024. Scope of investigation: Therapeutic apps for alcohol dependence and reducing alcohol intake that have manufacturing and marketing approval and insurance coverage in Japan.

■ About Therapeutic Apps

Therapeutic apps are smartphone apps that are used as medical devices and they are confirmed as having the same levels of effectiveness and safety as pharmaceutical treatments. A medical practitioner “prescribes” an app to a patient who then downloads it onto their smartphone. Unlike general healthcare apps, therapeutic apps have a specific medical purpose, such as preventing, diagnosing, or treating an illness, and they are known professionally as “digital therapy” (DTx). As programmed medical devices for treating illness, they are categorized as medical devices and require the approval (or authorization) of the Ministry of Health, Labour and Welfare.

■ About CureApp Inc.

Founded in 2014 by two physicians, CureApp, Inc. is a manufacturer of medical devices that is involved in the research and development, production, and sale of therapeutic apps for smartphones, which have demonstrated their effectiveness in clinical trials and are prescribed by doctors to patients at medical clinics. In 2020, it developed the world's first*² smartphone-based medical device software for disease treatment to receive manufacturing and marketing approval and insurance coverage in the field of smoking cessation. Following this, in April 2022, it was the first in the world*³ to receive manufacturing and marketing approval in the field of hypertension, followed by insurance coverage in September of the same year. It is also proceeding with the development of therapeutic apps for a number of other diseases, including NASH, alcohol dependence, cancer, chronic heart failure, and chronic lower back pain. Additionally, it operates the assure mobile health program, a health promotion service for private companies, which is currently being implemented at 380 companies.

*2. Based on an investigation by CureApp. Timing of investigation: December 2020. Scope of investigation: Therapeutic apps for nicotine dependence that have manufacturing and marketing approval and insurance coverage.

*3. Based on an investigation by CureApp. Timing of investigation: September 2022. Scope of investigation: Therapeutic apps for hypertension that have manufacturing and marketing approval and insurance coverage.

■ About Sawai Group Holdings Co., Ltd.

Sawai Group Holdings Co., Ltd. is a group of healthcare companies that advance sustainably together with society under the corporate philosophy of “Always putting healthier lives first.” In order to create a world where as many people

as possible can live and participate actively in society with peace of mind, we will contribute to realizing longer, healthier lives through the manufacture and sale of pharmaceuticals, primarily by Sawai Pharmaceutical Co., Ltd., and through new businesses.

◆ Contact Information ◆

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[References]**■ Background Behind the Treatment of Alcohol Dependence – Making Alcohol Reduction an Option Due to the Importance of Early Treatment**

Excessive alcohol consumption poses not only the physical risk of developing serious illnesses, including cancer, but also increases behavioral risks such as interpersonal trouble. If a person is unable to change their drinking habits and control the amount of alcohol they consume despite the clear possibility of suffering this type of harm, they may be suffering from alcohol dependence.

Previous approaches to treating alcohol dependence focused on abstinence, but many people are resistant to this method, making it difficult to provide treatment. Alcohol reduction has been advocated in Europe and the U.S. as a new approach which aims to treat alcohol dependent people at an early stage before the manifestation of serious physical, psychological, or social problems. In Japan, a manual for reducing alcohol intake*⁴ created by several relevant associations was issued in 2019. Furthermore, in February 2024, the Ministry of Health, Labour and Welfare released guidelines for alcohol consumption from a health perspective*⁵, showing that appropriate alcohol consumption is now recognized as an issue that needs to be addressed at a national level.

*4. https://www.jarukanren.com/pdf/201911_inshuryouteigen_chiryuu_poket.pdf (Japanese language only)

*5. <https://www.mhlw.go.jp/content/12200000/001211974.pdf> (Japanese language only)

■ The Possibilities of an Alcohol Reduction Therapeutic App – Aiming to Promote More Approachable Outpatient Care for Reducing Alcohol Consumption

Realizing the early treatment of alcohol dependence requires overcoming the resistance of patients toward visiting medical institutions by providing highly specialized treatment through non-specialist medical institutions (such as psychiatrists that do not specialize in alcohol dependence or regular medical clinics).



*One of the App's displays

Although the majority of current treatment for alcohol dependence is provided at specialist medical institutions, it is thought that in cases where patients have less serious levels of dependence, they will feel resistant to visiting this kind of institution and may avoid treatment altogether. Therefore, there is a need for broader care provided through non-specialist medical institutions, not only for realizing early treatment for alcohol dependence, but also to reduce the adverse effects of alcohol, even if by just a little, on people who are not diagnosed as dependent.

On the other hand, the regular medical clinics that will be expected to provide this early treatment need to handle large number of patients in short timeframes, so the current reality is that they do not have the time to provide the psychosocial treatment that forms the basis of treatment for alcohol dependence.

The App is used by patients based on objectives set with a physician. Patients record the amount of alcohol consumed each day into the App and then work to reduce this amount by following the recommendations it provides. The patient then revises the objectives together with their physician during regular appointments at a medical institution. At these appointments, the physician can check the patient's progress through their computer as a reference for revising objectives.

In this way, the App solves the time constraints of medical clinics by providing supplementary psychosocial treatment to enable the provision of highly specialized treatment. Going forward, it is expected that outpatient alcohol reduction treatment can become widely available at non-specialist medical

institutions.

The App aims to contribute to improving the health of many people who have issues with their relationship with alcohol by providing patients with suitable medical support in an approachable way.

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