



See the following press releases for details.
<https://www.sawai.co.jp/release/detail/625>
<https://www.sawai.co.jp/release/pdf/640>
<https://cureapp.blogspot.com/2024/02/nashcureapp.html>

New businesses

In addition to the core generic drug business, we are working to develop new businesses such as digital and medical devices with the aim of achieving sustainable growth for the Group. As a general healthcare corporate group that helps ensure healthy lives, we continue to take on the challenge of contributing to people's health from the field of pre-symptomatic illness and prevention to the field of treatments to expand the range of new options beyond drug therapy.

1. Non-invasive neuromodulation device, Relivion®

First in Japan to obtain marketing and manufacturing approval as a medical device for treatment of migraines during the acute phase

In December 2023, we were the first company in Japan to obtain marketing and manufacturing approval of the non-invasive neuromodulation device Relivion® as a medical device to treat migraines during the acute phase.

Neuromodulation is a treatment method to adjust nerve functions through electric and magnetic stimulation. Relivion® is worn on the head and relieves migraine pain by stimulating the nerves connected to that pain with electrical currents. As the sole distributor in Japan, we are further expanding treatment options for migraines during the acute phase beyond drug therapy.



Non-invasive neuromodulation device, Relivion®



Message from responsible officer

Expectations that this will lead to new treatments options for patients

Relivion® is the Group's first medical device business launch, and it drew the whole company together, particularly the Research and Development Division and Reliability Assurance Division, to address new issues, such as consulting with related authorities, applying for PMDA approval, and building a QMS system. More than three years after launching an examination in July 2020, we are truly happy to have obtained approval. Offering a new option for treating migraines, which are now mainly handled using drug therapy, enables us to provide patients suffering from migraines and medical professionals with a lot of value.

Through these initiatives, we have been able to build a system to handle medical devices in addition to the generic drug business. We aim to contribute to the realization of "always putting healthier lives first" and satisfy unmet medical needs by working to provide various treatment options.

Toyohiro Sawada, Ph.D.

Executive officer,
 Group Chief Product Strategy officer,
 Group Deputy Chief Research & Development officer, and General Manager of Group Product Strategy Department



2. PHR management app, SaluDi

Providing an app for an inter-industry collaborative verification project related to healthy urban development in Iizuka, Fukuoka

We are providing SaluDi for a verification project regarding healthy urban development that starts with PHR service. The project is being conducted jointly by Iizuka City and Japan Wellbeing Consortium member companies.

This project aims to enhance the health of local residents by capturing those uninterested in health, digitalizing guidance for combating metabolic syndrome, and supporting health and productivity through partnerships with local companies. SaluDi is being used as a health management app that can record and store vital statistics such as blood pressure and weight.

The project revealed that there was an increase in health awareness, as 72.8% of the 190 participating Iizuka City residents responded that "they were more conscious of health."

Summary of verification project

- 1 Increased levels of exercise and behavioral changes in residents**
Points awarded for regional trips and regional economic activities
- 2 Improved health consciousness of residents**
View PHR data and risk of developing illness on app

Leverages accumulated PHR data
 Used for guidance on combating metabolic syndrome, etc., for residents

Contributes to the future image of a healthy, happy city that Iizuka is aiming for

3. Non-alcoholic steatohepatitis (NASH) treatment app

Launch phase 3 clinical trial of treatment app that is expected to help treatment through lifestyle guidance



In January 2024, we launched a phase 3 domestic clinical trial of a non-alcoholic steatohepatitis (NASH) treatment app, for which we concluded a development and marketing license agreement with CureApp Inc. Although there is a risk that if NASH progresses it can result in liver cancer, there is no established drug therapy, and it is difficult to maintain effective diet and exercise treatment methods.

This app encourages behavioral changes using learning content for individual patients. Furthermore, the app makes it possible for not only patients themselves but also physicians to manage records, such as changes in the patient's weight, allowing for optimal treatment and lifestyle guidance. Through the phase 3 clinical trial, which targets patients for whom physicians determined lifestyle guidance could be an effective treatment, we will examine what percentage of participants have seen an improvement 48 weeks later using the app.