

August 3, 2020

Save Medical Corporation  
Sumitomo Dainippon Pharma Co., Ltd.

**Save Medical and Sumitomo Dainippon Pharma Announce Signing of  
Joint Development Agreement for Mobile App for Management of  
Type 2 Diabetes and Commencement of Clinical Study**

Save Medical Corporation (Head Office: Chuo-ku, Tokyo; CEO: Shotaro Asano; hereinafter, "Save Medical") and Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura) announced today that the two companies have reached an agreement to jointly develop a mobile app for the diabetes management for patients with type 2 diabetes (hereinafter, "the App") and that Save Medical has commenced a clinical study for the App in Japan.

Used under doctors' guidance, the App supports type 2 diabetes patients better managing the disease, facilitate behavioral changes, and consequently improve clinical parameters. The aforementioned clinical study is designed to evaluate the efficacy and safety of the App for patients with type 2 diabetes. Recent years have seen growing worldwide attention on digital therapeutics (DTx), evidence-based therapeutic interventions driven by software programs like the App.

Save Medical intends to implement evidence-based DTx by accelerating the development of the App through this joint development agreement.

Sumitomo Dainippon Pharma, on the other hand, has chosen the Diabetes area as one of its focus areas in Japan and is marketing and developing multiple therapeutic agents for type 2 diabetes with differing mechanisms of action. Sumitomo Dainippon Pharma will support Save Medical by financing part of the expenses for this joint development project and sharing some of its knowledge and experience in pharmaceutical development.

With this agreement, the two companies aim to contribute to the progress of healthcare by adding a new modality to the treatment of type 2 diabetes and offering new values to afflicted patients.

<Reference information>

**About mobile apps for management for diabetic patients**

Patients log their daily activities related to diabetes management (meal photo, exercise, body weight, medication, blood pressure, and glucose level) to the App. Upon logging, patients will receive chatbot messages which help them facilitate behavior changes. To

reduce the burden on patients, text input is kept to a minimum.

By providing individual patients with pertinent follow-ups, improvement of clinical parameters is expected as patients gain more awareness of disturbances in their lifestyles and poor compliance that often occur between hospital visits, which are expected to result as the change in their behavior.

Unlike other apps, the App is intended to be used under medical doctors' guidance and endorsement, which will motivate patients to continue with their treatment and efforts to change their behavior.

### **About the clinical study (Phase 3) in Japan**

This clinical study is aimed at evaluating the efficacy and safety of the App for patients with type 2 diabetes. The study is an intergroup study between a standard type 2 diabetes therapy group and a group of patients combining the App with standard therapy, using the change in HbA1c as the primary endpoint. It is expected that the App will be approved in Japan as a medical device program by the end of fiscal year 2022.

### **About digital therapeutics (DTx)**

DTx are defined as evidence-based therapeutic interventions driven by software programs to prevent, manage, or treat a medical disorder or disease. To optimize patient care and outcomes of therapy, they may be used on their own and also in combination with pharmaceutical products, medical devices, or other therapies.

In Japan, with the enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices in 2014, stand-alone programs (software), including mobile apps, are treated as a medical device.

### **About Save Medical Corporation**

Guided by its corporate mission, "To develop DTx and implement them to the society," Save Medical Corporation aims to develop evidence-based information technology products to "save patients", "save medical resources", and "save healthcare costs".

URL : <https://savemedical.jp/>

### **About Sumitomo Dainippon Pharma Co., Ltd.**

Sumitomo Dainippon Pharma Co., Ltd. is actively engaged in research and development of new drugs to live up to its corporate mission, "To broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide."

In business fields other than pharmaceuticals, too, we are working to provide new values that will contribute to "wide-ranging well-being". With a focus on preventive medical care and patient care, as well as treatment of diseases, Sumitomo Dainippon Pharma aims to launch new businesses in these fields by building a platform that is geared chiefly toward areas in which we can create synergies with our own pharmaceutical business.

URL : <https://www.ds-pharma.co.jp/>

Contact:

Save Medical Corporation

E-mail: [info@savemedical.jp](mailto:info@savemedical.jp)

TEL: +81-3-6661-2317

Corporation Communications

Sumitomo Dainippon Pharma Co., Ltd.

TEL: +81-6-6203-1407 (Osaka); +81-3-5159-3300 (Tokyo)