

Hyfe Cough Monitoring Primary Endpoint in Pivotal Clinical Trial for First Digital Therapeutic to Treat Chronic Cough

For only the second time globally, wearable data has been accepted by a major regulator as the primary endpoint in a pivotal clinical trial.

WILMINGTON, DE, UNITED STATES, June 15, 2026 /EINPresswire.com/ -- [Hyfe, Inc.](#), the global leader in continuous cough monitoring, today announced regulatory agreement with Japan's Pharmaceuticals and Medical Devices Agency (PMDA) on the use of the company's [CoughMonitor Suite\(CMS\)](#) as the primary endpoint measurement tool in the upcoming pivotal clinical trial of a prescription digital therapeutic (DTx) for chronic cough, co-developed with KYORIN Pharmaceutical Co., Ltd. The trial is sponsored by KYORIN.



This is the first time a fully automated cough monitoring tool will serve as the primary endpoint in a pivotal clinical trial. CoughMonitor Suite - a wrist-worn wearable paired with a clinical-research dashboard - has previously been deployed in more than 55 studies as an exploratory endpoint, and as a primary endpoint in Phase 1 and field research. Agreement by a major drug regulator at the pivotal stage represents a regulatory landmark for objective, continuous cough measurement and establishes a first-in-class pathway in a market where no PMDA guidance specific to digital health endpoints previously existed.

The pivotal trial is a single-blind, controlled, multi-site study to evaluate the efficacy and safety of DTx when used in conjunction with Standard of Care in patients with chronic cough as a treatment for chronic cough patients who have shown insufficient improvement on existing therapies. The trial is designed to generate the clinical evidence intended to support PMDA review of the DTx, which is anticipated as a Class II Software as a Medical Device (SaMD).

"PMDA's acceptance of the CoughMonitor Suite in this pivotal trial is a defining moment for the field of digital endpoints in life sciences, and for Hyfe. After years of validation as an exploratory tool inside major pharma trials, our technology now stands on its own in a regulated therapeutic development program. This sends a strong signal to the industry that automated longitudinal

cough data is mature enough to anchor pivotal-stage decision making.”

- Tamsin Chislett, CEO, Hyfe, Inc.

“Chronic cough is one of the most underserved conditions in respiratory medicine, and patients in Japan have very limited options when standard treatments fall short. Partnering with Hyfe allows us to build the world's first prescription digital therapeutic for chronic cough on a measurement foundation that meets the scientific precision required by PMDA of pivotal evidence. We see this trial as a milestone not only for our DTx program, but for the broader integration of digital health into Japanese clinical practice.”

- Yutaka Ogihara, President & CEO, KYORIN Pharmaceutical Co., Ltd.

If the trial meets its endpoints and PMDA approval is obtained, the resulting product will be the world's first prescription digital therapeutic for chronic cough. PMDA acceptance also establishes a regulatory reference point for objective, continuous cough endpoints, one that Hyfe expects to inform endpoint strategies as the field matures.

About Hyfe, Inc.

Hyfe is the global leader in continuous cough monitoring, the only company delivering both objective cough measurement and digital cough treatment. Used in 55+ trials, Hyfe’s easy-to-use tools are privacy-preserving and built for real-world use, revealing patterns, triggers, and treatment response that short-term snapshots miss. Built on the world’s largest verified cough dataset, the extensively validated CoughMonitor Suite for clinical trials serves pharma companies, CROs, and healthcare providers worldwide. In addition, "[ResolveDTx](#)," currently under development outside of Japan, is a digital therapeutic product for chronic cough. More information is available at hyfe.com.

About KYORIN Pharmaceutical Co., Ltd.

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. More

Julian Circo

Hyfe Inc.

[email us here](#)

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