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Notice Regarding the Initiation of a Confirmatory Study for "KRP-DC125," a Digital Therapeutic (DTx) for Chronic Cough

KYORIN Pharmaceutical Co., Ltd. announced today that the initiation of a confirmatory study (pivotal study) for KRP-DC125, a digital therapeutic designed for the treatment of chronic cough.

KRP-DC125 is being developed in collaboration with Hyfe Inc. (Wilmington DE, CEO: Tamsin Chislett). It is based on non-pharmacological therapies aimed at alleviating chronic cough and integrates Hyfe's cough monitoring tools.

The study is a multicenter, randomized, single-blind, comparative trial designed to evaluate the efficacy and safety of KRP-DC125 when used in conjunction with standard medical care in chronic cough patients with insufficient response to existing treatments. The study will assess the KRP-DC125's safety profile and its effectiveness in improving cough symptoms. Following the completion of this study, KYORIN plans to submit an application for manufacturing and marketing approval in Japan.

By developing KRP-DC125, KYORIN aims to provide a new, innovative treatment option for patients suffering from the burden of chronic cough.

The impact on business performance for the fiscal year ending March 2027 is to be negligible.

[Reference]

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 <https://hyfe.com/>

About Chronic Cough

Coughing that persists for eight weeks or longer is defined as chronic cough. It is associated with various underlying conditions, such as cough variant asthma, atopic cough, and gastroesophageal reflux disease (GERD).

In clinical practice, pharmacological therapy targeting the underlying cause is the most common treatment approach. However, it has been reported that some patients do not achieve sufficient relief even with medication, while in other cases, the underlying cause cannot be clearly identified*.

While non-pharmacological therapies are known to be effective in alleviating chronic cough, they face practical barriers to widespread adoption, including the significant time and effort required for treatment and challenges related to healthcare reimbursement.

*The JRS Guidelines for the Management of Cough and Sputum 2025 [2nd Edition]