

To all persons concerned

November 14, 2018
Ohara Pharmaceutical Co., Ltd.

**Adoption as a Practical Realization Development Type of
the Cyclic Innovation for Clinical Empowerment by
the Japan Agency for Medical Research and Development**

Ohara Pharmaceutical Co., Ltd. (Head Office: Koka-shi, Shiga Japan; CEO: Seiji Ohara; hereinafter, referred to as “Ohara”) is pleased to announce that on October 16, 2018, our development plan for the practical application of OP-724, a drug for the treatment of hepatic cirrhosis caused by hepatitis B and C viruses infection, was adopted by the public offering project of the Japan Agency for Medical Research and Development (hereinafter, referred to as “AMED”), as a practical realization development type in the general-type of the (3rd) “Cyclic Innovation for Clinical Empowerment (hereinafter, referred to as “C*i*CLE”)” in FY2018.

C*i*CLE, which is implemented by AMED, is a project that mobilizes all of Japan’s capabilities through industry-academia-government collaboration, with the aim of promoting the implementation of research and development that responds appropriately to medical needs, establishing infrastructure (including human resources) that fundamentally innovates acceleration of the practical realization of drug discovery, and creating an environment that strongly promotes open innovation and venture development in the field of medical research and development.

An overview of the practical realization development type that has been adopted by the AMED on this occasion is as follows:

- Project title: Research and development of an innovative antifibrotic drug that improves the life prognosis of hepatic cirrhosis
- Representative company: Ohara Pharmaceutical Co., Ltd.

Website of AMED related to the adoption of C*i*CLE projects (Japanese only):

https://www.amed.go.jp/koubo/07/01/0701C_00001.html

Following this adoption for C*i*CLE by AMED, Ohara will accelerate the development of OP-724, so that it can be provided to patients who are suffering from hepatic cirrhosis without further delay.

【About OP-724】

OP-724 is a compound developed by PRISM BioLab (PRISM BioLab Development Code: PRI-724), which acts as a CBP/beta catenin antagonist that inhibits activation of the Wnt/beta-catenin signaling pathway. Although it was originally developed as an anticancer drug, a study performed at the Tokyo Metropolitan Institute of Medical Science using a hepatic cirrhosis mouse model independently developed by the Institute confirmed that OP-724 displays antifibrotic effects, resulting in an improvement in hepatic histology. Based on these findings, an investigator-initiated phase I clinical trial has been completed in patients with hepatic cirrhosis in Japan, at the Tokyo Metropolitan Cancer and Infectious Diseases Center Komagome Hospital, with the support of the Acceleration of Transformative Research for Medical Innovation (ACT-M) of AMED Medical Research and Development Programs Focused on Technology Transfer. Currently, an investigator-initiated clinical trial is underway which is centered on the Tokyo Metropolitan Cancer and Infectious Diseases Center Komagome Hospital, with development support provided by the Kyushu University Center, as Seeds C in the AMED Bridging Research Accelerating Network Program. On May 24 of the current year, Ohara in-licensed the development and commercialization rights of OP-724 from PRISM BioLab, and is currently leading its development in Japan. With the support of many medical institutions, Ohara will endeavor to promote the further development of OP-724, in order to promptly obtain marketing authorization for the treatment of hepatic cirrhosis caused by hepatitis B and C viral infections.

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