



April 25, 2025

Company Name: Rohto Pharmaceutical Co., Ltd.
Representative: Masashi Sugimoto, President and COO
(Code: 4527, Tokyo Prime Market)
Contact: Yukiko Tobe, General Manager,
Public Relations & CSV Promotion Department
(TEL. +81-6-6758-1211)

Announcement of the Initiation of Domestic Phase II Clinical Trial for Heart Failure Treatment "ADR-002K"

Rohto Pharmaceutical Co., Ltd. (Headquarters: Osaka; President and COO: Masashi Sugimoto) announces the initiation of a domestic Phase II clinical trial (hereinafter referred to as "the Trial") for the regenerative medicine product-code, "ADR-002K", targeting severe heart failure caused by ischemic heart disease.

Details:

In recent years, the number of heart failure patients has been increasing due to an aging society. It is well known that heart failure resulting from ischemic heart disease has a particularly poor prognosis. It has been reported that patients with a left ventricular ejection fraction (LVEF) below 40% face a significantly worsened life expectancy, highlighting the urgent need for new treatment options.

To address this unmet medical needs, Rohto has been developing "ADR-002K", a regenerative medicine product derived from adipose-derived mesenchymal stem cells. It is expected to improve cardiac function and extend life expectancy when used in combination with coronary artery bypass grafting (CABG). Following the confirmation of safety in the Phase I trial, the Phase II trial will evaluate both the efficacy and safety in patients with severe heart failure.

We will continue to work on the development of innovative medical technologies, contributing to human health by improving patients' quality of life and advancing treatment options in cardiovascular medicine.