

Shionogi and Rohto Pharmaceutical Co.,Ltd. Enter into Lisence Agreement regarding “Cellular and Tissue-based Products” Candidate ADR-001

OSAKA, Japan, September 13, 2018 –Shionogi & Co., Ltd. (Head Office: Osaka, Japan; hereafter "Shionogi") today announced Shionogi and Rohto Pharmaceutical Co.,Ltd.(Head Office:Osaka, Japan, hereafter “Rohto”) have entered into lisence agreement for clinical development and commercialization of ADR-001 for the treatment of liver cirrhosis in Japan.

Liver cirrhosis is a pathological condition cased by degeneration of hepatocytes and subsequent fibrosis which leads to severe deterioration of liver function. It is known that liver cirrhosis is the common risk factor of liver cancer. There are only symptomatic treatments for advanced liver cirrhosis, and the effective new treatment is necessary.

ADR-001, discovered by Rohto, is one of the “Cellular and Tissue-based Products” which is prepared from mesenchymal stromal cells (MSC) derived from allogeneic adipose tissue. Adipose tissue contains many MSC and is less invasive to obtain MSC than bone marrow. From these characteristics, it is expected that ADR-001 can be manufactured and stocked on a large scale and this treatment can be provided smoothly to patients. Rohto is currenty conducting a Phase I /II study in patients with decompensated liver cirrhosis.

Under the terms of the agreement, Shionogi will be responsible for clinical development after Phase I /II study and commercialaization of ADR-001 for liver cirrhosis in Japan. Rohto will be responsible for supplying the product. Shionogi will make an upfront payment to Rohto, and Rohto will be eligible to receive additional development milestones and royalties.

About Shionogi & Co., Ltd.

Shionogi & Co., Ltd. is a Japanese major research-driven pharmaceutical company dedicated to bringing benefits to patients based on its corporate philosophy of “supplying the best possible medicine to protect the health and wellbeing of the patients we serve.” The company currently markets products in several therapeutic areas including anti-infectives, pain, cardiovascular diseases and gastroenterology. Our pipeline is focused on infectious disease, pain and CNS. For more information on Shionogi & Co., Ltd., visit www.shionogi.co.jp/en.

Forward-Looking Statements

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties

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which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

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