Announcement of Submission of New Drug Application for Epadel in China

This material is an English translation of the press release to be issued on July 2, 2024 in Japanese, and the Japanese release is given priority regarding content and interpretation.

July 2, 2024

Mochida Pharmaceutical Co., Ltd.

Mochida Pharmaceutical Co., Ltd. (Head office: Tokyo, Japan, President: Naoyuki Mochida, hereinafter: Mochida) announced that Mochida submitted a New Drug Application to the China National Medical Products Administration (NMPA) for Epadel S (development code: MND-21), a highly purified eicosapentaenoic acid (EPA) ethyl ester formulation that is being jointly developed in China by Mochida and Sumitomo Pharma (Suzhou) Co., Ltd., a Chinese subsidiary of Sumitomo Pharma Co., Ltd.

As the clinical phase III trial conducted in patients with severe hypertriglyceridemia in China has shown positive results, Mochida has submitted a New Drug Application for Epadel S.
Additionally, Mochida has entered into a distribution agreement for Epadel S in China with Meiji Seika Pharma Co., Ltd. (hereinafter: Meiji) in 2024. After approval, Mochida will supply the product to Meiji, which will distribute it through its affiliated partner in China, MAXMIND Bio-Technology (Hainan) Co., Ltd.

Mochida is committed to contributing to the improvement of the quality of life for Chinese patients with hypertriglyceridemia through Epadel S.

About Epadel

Epadel (generic name: icosapent) is a highly purified EPA ethyl ester formulation developed by Mochida as the world's first medical drug. The product is available in Epadel Capsules, Epadel S, and Epadel EM Capsules forms. Epadel S is indicated for "Hyperlipidemia" and "Ulcer, pain and chilliness associated with arteriosclerosis obliterans" in Japan. The active pharmaceutical ingredient is supplied by Nissui Corporation, which has advanced EPA purification technology and mass production capability. Since its launch in 1990, it has been taken by many patients.