Fuji Chemical Industries

富士化学工業株式会社

55 Yokohoonji, Kamiichi-machi,
Nakaniikawa-gun,
Toyama 930-0355, Japan
Tel: +81(0)76-472-2323
www.fujichemical.co.jp/english/

News Release

January 7, 2025

Additional Indication of Sclerotherapy of Venous Malformations for "OLDAMIN® for Injection 1g" (Esophageal Variceal Sclerotherapy and Gastric Variceal Regression Agent) in Japan

TOKYO, December 27. 2024 – Fuji Chemical Industries Co., Ltd. (Head Office: Toyama/President & CEO: Hiroshi Nishida, "FUJI") announced that FUJI received approval for the additional indication of "Sclerotherapy of venous malformations" for the esophageal variceal sclerotherapy and gastric variceal regression agent "OLDAMIN® for Injection 1g" (generic name: monoethanolamine oleate; "OLDAMIN") manufactured and distributed by FUJI and marketed by ASKA Pharmaceutical Co., Ltd. (Head Office: Minato-ku, Tokyo/Representative Director: Sohta Yamaguchi, "ASKA"), a subsidiary of ASKA Pharmaceutical Holdings Co., Ltd. (TSE: 4886).

FUJI would like to express its deepest gratitude for the efforts of all the physicians who participated in the investigator-initiated clinical trial with Dr. Tadashi Nomura, Department of Plastic Surgery / Aesthetic Surgery, Kobe University Hospital, and Dr. Mine Ozaki, Department of Plastic & Reconstructive Surgery/ Aesthetic Surgery, Kyorin University Hospital, as coordinating physicians, and for the cooperation of patients who participated in the trial, and for the support of the Japan Agency for Medical Research and Development (AMED).

The drug has been approved for "Hemostasis of esophageal variceal bleeding/Sclerotherapy for esophageal varices/ Regression of gastric varices," and has now been approved for the additional indication of "Sclerotherapy of venous malformations." Venous malformations are congenital vascular lesions characterized by a predominant venous component and a gradual growth pattern. They can occur anywhere in the body and are often asymptomatic. However, they can cause a variety of site-specific symptoms and dysfunctions. In particular, venous malformations are common in the facial region and can cause significant cosmetic concerns beginning in childhood.

Clinical trials of OLDAMIN for this disease were conducted as investigator-initiated trials at eight medical institutions from January 2021, with the Clinical & Translational Research Center, Kobe University Hospital as the coordinating office for the trials. Based on the results

Fuji Chemical Industries

富士化学工業株式会社

55 Yokohoonji, Kamiichi-machi,
Nakaniikawa-gun,
Toyama 930-0355, Japan
Tel: +81(0)76-472-2323
www.fujichemical.co.jp/english/

News Release

January 7, 2025

of the trials, FUJI filed an application for approval to the authorities in February 2024 with the cooperation of ASKA.

FUJI and ASKA hope the approval will be of some help by providing a new treatment option for patients with venous malformations.

We will contribute to society by developing clinically effective and safe pharmaceutical products.

＜Contact information regarding this matter＞
Kiyotaka Moriizumi, Business Development Department
Fuji Chemical Industries Co., Ltd.
55 Yokohoonji, Kamiichi-machi, Nakaniikawa-gun, Toyama-Pref. Japan
Tel: +81-76-472-2323
Email: info@fujichemical.co.jp
＜URL＞
Fuji Chemical Industries Co., Ltd.
www.fujichemical.co.jp/English/