大日本住友製薬

News Release

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Sumitomo Dainippon Pharma Co., Ltd.

# Sumitomo Dainippon Pharma Submits an Application of RETHIO® for an Additional Indication of Conditioning Treatment Prior to Autologous Hematopoietic Stem Cell Transplantation for Malignant Lymphoma

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura hereinafter called "Sumitomo Dainippon Pharma") has announced today that on March 29 the company applied for a partial change in the marketing approval previously acquired in Japan for RETHIO® 100 mg for I.V. infusion (generic name, thiotepa; hereinafter called "RETHIO"). The change applied for this time involves an additional indication of RETHIO for conditioning treatment prior to autologous hematopoietic stem cell transplantation (auto-HSCT) for malignant lymphoma.

RETHIO is a drug indicated for conditioning treatment prior to auto-HSCT for pediatric malignant solid tumors. Sumitomo Dainippon Pharma obtained the marketing approval for this drug on March 26, 2019 and plans to launch it after NHI drug price listing.

Malignant lymphoma, a hemocytes-derived cancer, is a disease that lymphocytes, a subpopulation of leukocytes (white blood cells), become cancerous. This disease occurs typically in lymphoid tissues, such as lymph nodes, spleens, and tonsils, but it also often develops in other sites. It has been reported that the incidence of malignant lymphoma is around ten in 100,000 persons in Japan annually, the most common hematapostema in Japanese adults. As with conditioning treatment prior to autologous HSCT for pediatric malignant solid tumors, the Evaluation Committee on Unapproved or Off-labeled Drugs with High Medical Needs of the Ministry of Health, Labour and Welfare (MHLW) determined similarly high medical need in conditioning treatment prior to auto-HSCT for malignant lymphoma. Thus, Sumitomo Dainippon Pharma conducted Phase 1 trials in Japan and subsequently applied for the additional indication.

Sumitomo Dainippon Pharma believes that, upon approval of its additional indication, this drug will contribute to improved healthcare as a new treatment option for patients indicated for conditioning treatment prior to auto-HSCT for malignant lymphoma, a therapeutic area with high unmet medical need.

<Reference information>

About autologous hematopoietic stem cell transplantation (auto-HSCT)

Autologous hematopoietic stem cell transplantation is a therapy that aims to reconstruct hematopoietic capacity via intravenous transfusion of normal hematopoietic stem cells of the patient

himself/herself after eradicating intractable cancers by conditioning myeloablative treatment prior to transplantation using maximum levels of anti-cancer drugs or radiation.

About the Evaluation Committee on Unapproved or Off-labeled Drugs with High Medical Needs

The Evaluation Committee on Unapproved or Off-label Drugs with High Medical Needs is a committee established to promote the development of unapproved or off-label drugs by pharmaceutical companies that are approved for use in Europe and the United States, etc., but not approved in Japan. It is organized under the Ministry of Health, Labour and Welfare of Japan and consists of academic experts in medical and pharmaceutical fields.

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