Sumitomo Dainippon Pharma

News Release

March 25 2020

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Announces the Approval 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") announced today that, on March 25, 2020, it obtained approval for a partial change in the marketing approval previously acquired in Japan for RETHIO® 100 mg for I.V. infusion (generic name: thiotepa; hereinafter, "RETHIO®"). The change approved at 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 that Sumitomo Dainippon Pharma launched on May 28, 2019, for an indication of conditioning treatment prior to auto-HSCT for pediatric malignant solid tumors. Malignant lymphoma, which is related to this additional indication, is a type of hemocytes-derived cancer in which lymphocytes, a subpopulation of leukocytes (white blood cells) become cancerous, and typically occurs in lymphoid tissues, such as lymph nodes, spleens, and tonsils, but it often develops in other sites as well. It has been reported that 34,240 persons affected with this disease in FY2016*, making it the most common hematological malignancy in Japanese adults. As with conditioning treatment prior to auto-HSCT for pediatric malignant solid tumors, for which approval was received in 2019, 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 for thiotepa in conditioning treatment prior to auto-HSCT for malignant lymphoma. Accordingly, Sumitomo Dainippon Pharma conducted Phase 1 trials in Japan and subsequently applied for approval of the additional indication.

Sumitomo Dainippon Pharma believes that this approval will allow it to offer a new treatment option for malignant lymphoma patients who need conditioning treatment prior to auto-HSCT, a therapeutic area with a high unmet medical need, thus contributing to improved healthcare.

** Cancer Incidence of Japan 2016, Cancer and Disease Control Division, Health Service Bureau, MHLW*

<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 MHLW of Japan and consists of academic experts in medical and pharmaceutical fields.

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