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Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Submits New Drug Application for Thiotepa in Japan for Conditioning Treatment Prior to Autologous Hematopoietic Stem Cell Transplantation for Pediatric Solid Tumors

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura hereinafter called "Sumitomo Dainippon Pharma") announced today that it submitted a new drug application for thiotepa (generic name, product code: DSP-1958) in Japan on July 3, for conditioning treatment prior to autologous hematopoietic stem cell transplantation (HSCT) for pediatric solid tumors.

Thiotepa is an antitumor alkylating agent that belongs to the ethyleneimine group and inhibits DNA synthesis. In Japan, Sumitomo Chemical Co., Ltd. launched this agent as Tesupamin® injection in 1958, which was then taken over by Sumitomo Pharmaceuticals Co., Ltd. (current Sumitomo Dainippon Pharma) in 1984. However, following the discontinued production of its active pharmaceutical ingredients in 2008, Sumitomo Dainippon Pharma discontinued its marketing in 2009, and the agent has not been available since then in Japan.

In Japan, thiotepa had no approved indication for conditioning treatment prior to autologous HSCT, but had been put to clinical use in combination with other chemotherapeutic agents by following the precedent set by the U.S. and Europe. In spite of the discontinuation of its marketing in 2009 in Japan, many requests for their use for this indication were made by academic societies and other parties concerned, as thiotepa was approved for conditioning treatment prior to HSCT in Europe in 2010. In response, the Evaluation Committee on Unapproved or Off-labeled Drugs with High Medical Needs of the Ministry of Health, Labour and Welfare of Japan (MHLW) determined that the medical need for thiotepa was high. Accordingly, the MHLW invited private companies to develop the agent for the indication, to which Sumitomo Dainippon Pharma replied in September 2013 and began conducting a Phase 1 study in Japan from November 2016 as a pharmacokinetic study, the results of which are included in the data attached to this application. Meanwhile, Sumitomo Dainippon Pharma is also preparing an application for approval of thiotepa for conditioning treatment prior to autologous HSCT for malignant lymphoma.

Sumitomo Dainippon Pharma expects that thiotepa, if approved, would be a new therapeutic option for patients in areas with high unmet medical needs, such as conditioning treatment prior to autologous HSCT for pediatric solid tumors, contributing to the treatment of patients with such symptoms.

<Reference information>

About hematopoietic stem cell transplantation (HSCT)

HSCT is a powerful adjuvant therapy that aims to reconstruct hematopoietic capacity via intravenous transfusion of normal hematopoietic stem cells after eradicating intractable cancer by

performing conditioning myeloablative treatment prior to transplantation using maximum levels of anti-cancer drugs or radiation. Since patients' own hematopoietic stem cells are collected and preserved beforehand, autologous HSCT is free from concerns about immunoreactions to transplanted hematopoietic stem cells. As such, this conditioning treatment prior to transplantation aims to eradicate tumor cells as much as possible through high-dose chemotherapy using anticancer drugs in doses that exceed the maximum tolerance of bone marrow. According to the Japanese Data Center for Hematopoietic Cell Transplantation (JDCHCT), the number of HSCT cases in Japan totaled 93,902 between 1986 and 2016, among which 33,527 cases were autologous HSCT.

About Pediatric Solid Tumors

According to the Practical guidelines for pediatric cancer 2016, approximately 2,500 new cases of pediatric cancer occur annually in Japan, with approximately 1,300 new cases of pediatric solid tumors (excluding hematopoietic organ tumors, such as leukemia). Compared to solid tumors in adults, pediatric solid tumors demonstrate favorable chemosensitivity. As a result, better outcome of high-dose chemotherapy combined with HSCT is expected, and transplantation is now being performed as a part of everyday clinical practice. According to the JDCHCT, the number of HSCT cases for pediatric sold tumor patients totaled 3,276 between 1991 and 2016, among which 3,058 cases were autologous HSCT.

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 by the MHLW and consists of academic experts in medical and pharmaceutical fields.

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