

NEWS RELEASE



March 18, 2021

Nippon Shinyaku and Menarini Group enter into an Exclusive License Agreement to Develop and Commercialize tagraxofusp in Japan

KYOTO, Japan, March 18, 2021 - Nippon Shinyaku Co., Ltd. (HQs: Kyoto, President: Shigenobu Maekawa) announced that it has entered into an exclusive license agreement for the development and commercialization of tagraxofusp in the territory of Japan with the Menarini Group (HQs: Florence, CEO: Elcin Barker Ergun). Tagraxofusp, is approved for the treatment of patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN) by the U.S. Food and Drug Administration and the European Medicines Agency.

BPDCN is a rare aggressive hematologic malignancy with an extremely poor prognosis. BPDCN treatment is based on intensive multiagent leukemia or lymphoma chemotherapy regimens in Japan. However, the median overall survival of patients with BPDCN is around 12 months, and new therapeutic agents are desired.

Tagraxofusp is a targeted therapy directed to CD123. Tagraxofusp was launched in January 2019 in the United States for the treatment of first-line or relapsed/refractory patients with BPDCN. Tagraxofusp was also approved in January 2021 in Europe for first-line patients with BPDCN. Tagraxofusp has a mechanism of action to induce apoptosis of cells by inhibiting protein synthesis by specifically targeting cancer cells that express CD123.

Nippon Shinyaku is dedicated to the development and commercialization of therapeutic agents and providing medical information, focusing on the field of hematologic cancer. According to this agreement, Nippon Shinyaku aims to contribute to the treatment for patients with BPDCN by starting the clinical development and providing tagraxofusp to patients suffering from BPDCN as soon as possible.

About Menarini Group

Menarini Group is a leading international pharmaceutical company with a presence in 140 countries, including a direct presence in 70 countries. Its global platform extends throughout Europe, U.S., Central America, Africa, The Middle East and Asia Pacific, and generates over \$4.2 billion in annual sales. Menarini is committed to oncology, with an already commercialized product in the U.S. and several new investigational drugs in development for

the treatment of a variety of tumors. For over 130 years, Menarini has been investing in the development, production and distribution of pharmaceuticals to serve patients and physicians around the world with a full portfolio of products covering a number of different therapeutic areas.

For further information, please refer to the company website: <https://www.nippon-shinyaku.co.jp/english/>