NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

December 22, 2025

ELZONRIS® I.V. Injection Receives Marketing Approval for the Treatment of Blastic Plasmacytoid Dendritic Cell Neoplasm in Japan

Kyoto, Japan, December 22, 2025 - Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters: Kyoto; President: Toru Nakai) today announced that the Ministry of Health, Labour and Welfare (MHLW) has approved ELZONRIS® I.V. Injection (Tagraxofusp (genetically recombinant)) for the treatment of Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) in Japan. Nippon Shinyaku acquired a license for ELZONRIS® from Menarini Group (Headquarters: Florence, CEO: Elcin Barker Ergun) in March 2021, and has been advancing its development in Japan.

BPDCN is a rare aggressive hematologic malignancy that has features of both leukemia and lymphoma, with characteristic skin lesions, lymph node involvement, and frequent spread to the bone marrow, with poor prognosis. In the absence of an approved treatment option, BPDCN treatment is based on intensive multiagent leukemia or lymphoma chemotherapy regimens in Japan. However, the median overall survival of patients with BPDCN continues to be short (less than 12 months) and new therapeutic agents are desired[1-2].

ELZONRIS® is a first-in-class CD123 targeted therapy that induces apoptosis of BPDCN cells by inhibiting protein synthesis by specifically targeting CD123 expressing BPDCN cells. Based on the results of Phase I/II trials conducted overseas in untreated and relapsed/refractory BPDCN patients, ELZONRIS® has been approved by the U.S. Food and Drug Administration for the treatment of BPDCN in adults and in paediatric patients 2 years and older in December 2018, and by the European Medicines Agency for adult patients with untreated BPDCN in January 2021. ELZONRIS® has already been approved in over 40 countries worldwide.

The marketing authorization is based on data from the domestic Phase I/II study in Japanese BPDCN patients as well as overseas Phase I/II trials conducted by Stemline Therapeutics Inc, of the Menarini Group.

Nippon Shinyaku will work to ensure appropriate access to ELZONRIS® for patients in need and expects that ELZONRIS® will contribute to the treatment of BPDCN.

We believe that by delivering ELZONRIS® to patients in need, we can contribute to the treatment of BPDCN in Japan.

Summary of Approval

Brand name	ELZONRIS® I.V. Injection
Generic name	Tagraxofusp (genetically recombinant)
Dosage Form and Content	Frozen solution: 1 vial (1 mL) containing 1000 μg tagraxofusp (genetically recombinant)
Indication	Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
Dosage and Administration	The usual dosage for adults and children aged 2 years or older is 12 μg/kg of tagraxofusp (genetically recombinant) administered by intravenous drip infusion over a period of 15 minutes once daily for 5 days, followed by a 16-day treatment suspension. This 21-day period constitutes one cycle, and administration is repeated in cycles

Reference

1. Pagano L et al, Blastic plasmacytoid dendritic cell neoplasm with leukemic presentation: an Italian multicenter study. Haematologica. 2013; 98: 239-246.
2. Lourdes Martín-Martín et al, Classification and clinical behavior of blastic plasmacytoid dendritic cell neoplasms according to their maturation-associated immunophenotypic profile. Oncotarget. 2015; 6: 19204–19216.

About CD123

CD123 is the interleukin-3 (IL-3) receptor alpha chain, a cell-surface protein involved in hematopoietic cell growth and differentiation. Normal hematopoietic cells express little or no CD123, whereas most BPDCN patient cells show marked overexpression of CD123.

About Nippon Shinyaku Co., Ltd.

Based on Nippon Shinyaku's business philosophy, "Helping people lead healthier, happier lives," we aim to be an organization trusted by the community through creating unique medicines that will bring hope to patients and families suffering from illness. Please visit our website (https://www.nippon-shinyaku.co.jp/english/) for products or detailed information.

About Menarini Group

The Menarini Group is a leading international pharmaceutical and diagnostics company, with a turnover of over $5.0 billion and over 17,000 employees. Menarini is focused on therapeutic areas with high unmet needs with products for cardiology, oncology, pneumology, gastroenterology, infectious diseases, diabetology, inflammation, and analgesia. With 18 production sites and 9 Research and Development centers, Menarini's products are available in 140 countries worldwide. For further information, please visit www.menarini.com.

Contact

Corporate Communications Dept., Nippon Shinyaku Co., Ltd.
e_mail_kouhou@po.nippon-shinyaku.co.jp