

NEWS RELEASE



March 18, 2026

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

Kyoto, Japan, March 18, 2026 - Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters: Kyoto; President: Toru Nakai) announced today that it has launched ELZONRIS® I.V. Injection (Tagraxofusp (genetically recombinant)) for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) 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)¹⁻² and new therapeutic agents are desired.

ELZONRIS® is a recombinant fusion protein of diphtheria toxin and human interleukin-3 (IL-3). It exerts its antitumor effect by being internalized into tumor cells expressing CD123, which is the IL-3 receptor alpha subunit (IL-3R α), inhibiting protein synthesis in the target cells and inducing apoptosis. CD123 has been reported to be expressed in many hematopoietic tumors, and its expression is particularly high in blastic plasmacytoid dendritic cell neoplasm (BPDCN) cells compared to other hematopoietic tumors.

Furthermore, ELZONRIS® is approved as a treatment for BPDCN in over 40 countries worldwide, including Europe and the United States.

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. This follows the marketing approval of ELZONRIS®, which was granted by the Ministry of Health, Labour and Welfare (MHLW) on December 22, 2025.

Nippon Shinyaku believes that it will contribute to the treatment of BPDCN by delivering ELZONRIS® appropriately to healthcare professionals and their patients who need it.

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.

Summary of Approval

Brand name	ELZONRIS® I.V. Injection
Generic name	tagraxofusp (genetically recombinant)
Date of approval	December 22, 2025
Date of NHI reimbursement price listing	March 18, 2026
Date of launch	March 18, 2026
Number of approval	30700AMX00261000
Dosage form and content	Frozen solution: 1vial (1mL) containing 1000µg 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
NHI reimbursement price	JPY 3,607,878/vial
Packaging unit	1vial

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.

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