

May 20, 2020

## **Launch of Velexbu<sup>®</sup> Tablet 80mg, a Bruton's Tyrosine Kinase Inhibitor in Japan**

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President, Representative Director: Gyo Sagara; "ONO") announced today that ONO has launched Velexbu<sup>®</sup> (generic name: tirabrutinib hydrochloride) Tablet 80mg ("Velexbu"), a Bruton's tyrosine kinase ("BTK") inhibitor, for the treatment of recurrent or refractory primary central nervous system lymphoma in Japan.

Primary central nervous system lymphoma (PCNSL) is a malignant lymphoma in which the lesion is localized in the cerebrospinal cord (including the eyes) at the first onset. The signs and symptoms presented by patients with PCNSL vary depending on the site of the lesion, and include localized neuropathy, neuropsychiatric symptoms, symptoms associated with increased intracranial pressure, seizure, eye symptoms, headache, difficulty in movement, cranial neuropathy and radiculopathy.

Currently, untreated PCNSL patients receive high-dose methotrexate-based treatment followed by whole-brain radiation therapy, by which a certain patient population shows long-term remissions, but many patients will relapse. There are also refractory patients who do not respond to the currently available drug treatment. Standard treatment has not been established for patients with recurrent or refractory PCNSL, and treatment options are limited for them. Therefore, a new treatment drug is expected for patients with recurrent or refractory PCNSL<sup>\*1</sup>. Velexbu is the first BTK inhibitor approved in the world for the treatment of recurrent or refractory PCNSL for which no standard of care has been established.

It is estimated that there are approximately 980 new cases with PCNSL per year in Japan<sup>\*2, 3</sup>.

\*1: Practical Guidelines for Neuro-Oncology 2019

\*2: Neurol Med Chir (Tokyo). 2017;57(Supplement 1):9-102.

\*3: Jpn J Neurosurg VOL.24 NO.10 2015.10

On November 27, 2019, ONO also submitted an application of Velexbu in Japan for the treatment of Waldenstrom macroglobulinemia (WM) and lymphoplasmacytic lymphoma (LPL).

### **About Velexbu**

Velexbu (tirabrutinib hydrochloride), discovered and developed by ONO, is a highly selective, oral BTK inhibitor and has been developed for the treatment of patients with B-cell tumors and autoimmune diseases in Japan. B-cell receptor (BCR) signaling plays a core role in the survival, activation, proliferation, maturation and differentiation of B-cell lymphocyte. The BCR signaling pathway is known to be permanently activated, particularly in B-cell non-Hodgkin lymphoma (B-NHL) and chronic lymphocytic leukemia (CLL). Velexbu is expected to have a therapeutic effect because it inhibits BTK, a mediator located downstream of BCR.

In December 2014, ONO out-licensed tirabrutinib hydrochloride to Gilead Sciences, Inc. (Gilead) to allow the right to develop and commercialize the product in all countries of the world, except Japan, South Korea, Taiwan, China and ASEAN countries where ONO retains the development and commercialization rights of the product.

## **Overview of Velebru® Tablet 80mg**

Product Name	Velebru® Tablet 80mg
Generic name (JAN)	tirabrutinib hydrochloride
Indication	Relapsed or refractory primary central nervous system lymphoma
Dosage and administration	Usually, for adults, administer at 480 mg of tirabrutinib orally once a day in the fasting. The dose should be decreased based on patients' condition.
Approval date	March 25, 2020
NHI price listing date	May 20, 2020
NHI drug price	¥5,067.40/tablet
Manufacturer/distributor	Ono Pharmaceutical Co., Ltd.

## **Product photo**



## Contact

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