



Press Release

March 25, 2024

Nippon Shinyaku Co., Ltd.
Eli Lilly Japan K.K.

Announcement of Alliance Agreement for Pirtobrutinib, a Reversible Non-Covalent BTK Inhibitor in Japan

Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters: Kyoto; President: Toru Nakai) and Eli Lilly Japan K.K. (Eli Lilly Japan; Headquarters: Kobe; President and Representative Director: Simone Thomson) announced today that we have entered into an alliance agreement in Japan for pirtobrutinib, which Eli Lilly Japan is developing for the following indications:

- Mantle cell lymphoma (MCL)
- Chronic lymphocytic leukemia (CLL)

Based on this alliance agreement, in Japan, Eli Lilly Japan will be responsible for the supply of pirtobrutinib after obtaining the manufacturing and marketing approval, while Nippon Shinyaku will be responsible for distribution and sales, as well as information provision activities.

In signing the alliance agreement, as Nippon Shinyaku offers several hematological cancer drugs, it is expected that the addition of pirtobrutinib to its lineup will expand the treatment options for MCL and CLL, and strengthen the hematologic oncology field. Eli Lilly Japan believes that by collaborating with Nippon Shinyaku, which has experience in the field of hematological cancers, we will be able to contribute to the promotion of the proper use of pirtobrutinib by reliably providing information to healthcare professionals, and meet the unmet needs of more patients with MCL and CLL.

Nippon Shinyaku and Eli Lilly Japan will work closely together through the alliance agreement for pirtobrutinib to contribute to providing a new treatment option for patients with MCL and CLL in Japan.

About pirtobrutinib

Pirtobrutinib is a highly selective, non-covalent (reversible) inhibitor of the enzyme Bruton's tyrosine kinase (BTK). BTK is a validated molecular target found across numerous B-cell leukemias and lymphomas including mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL).^{1,2}

About Mantle Cell Lymphoma

MCL is a rare blood cancer and a form of non-Hodgkin lymphoma. MCL arises in B lymphocytes, a type of white blood cell. MCL frequently begins in B cells located in the mantle zone of the outer edge of lymph nodes. As the cancer progresses, it can spread to bone marrow, the spleen, the liver, or the digestive tract.³ Annually, about one in 200,000 people worldwide develop MCL³.

About Chronic Lymphocytic Leukemia

CLL is a form of slow-growing B-cell leukemia^{4,5}. In CLL, the cancer cells are present in the blood⁴.

About Nippon Shinyaku

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 Eli Lilly Japan

Eli Lilly Japan K.K. is a subsidiary of US-based Eli Lilly and Company. It contributes to medical treatment in Japan through the development, manufacture, import and sale of innovative pharmaceutical products that enable people to live longer, healthier, and more fulfilling lives, focusing on the therapeutic areas such as cancer, diabetes, musculoskeletal diseases, central nervous system diseases, autoimmune diseases, growth disorder, and pain. For more information, visit our website: <http://www.lilly.com/jp>

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