Press Release

November 16, 2026

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

Antineoplastic Agent “Jaypirca® 50 mg and 100 mg tablets” Approved for Expanded Indication in Chronic Lymphocytic Leukemia
– Now Available as a First-Line Treatment for Previously Untreated Patients –

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: Karla Alcazar) announced today, November 16, 2026, that Eli Lilly Japan has received approval in Japan for an expanded indication of the antineoplastic agent “Jaypirca® 50 mg and 100 mg tablets” (generic name: pirtobrutinib; hereinafter referred to as “Jaypirca”) for “chronic lymphocytic leukemia (including small lymphocytic lymphoma).”

Jaypirca is a Bruton tyrosine kinase (BTK) inhibitor that binds reversibly and noncovalently to BTK. BTK is a target molecule recognized in many B-cell lymphomas and leukemias, including chronic lymphocytic leukemia and mantle cell lymphoma.

This approval is based on the efficacy and safety results of two global Phase 3 studies, the BRUIN-CLL-313 study and the BRUIN-CLL-314 study. The BRUIN-CLL-313 study compared pirtobrutinib 200 mg orally once daily as monotherapy with bendamustine plus rituximab (bendamustine + rituximab arm: BR Arm) in 282 patients (including 12 Japanese patients) with untreated chronic lymphocytic leukemia and small lymphocytic lymphoma. For the primary endpoint of progression-free survival by central assessment, a statistically significant extension was observed in the pirtobrutinib arm compared with the BR Arm. The BRUIN-CLL-314 study compared pirtobrutinib 200 mg orally once daily as monotherapy (Pirtobrutinib Arm) with ibrutinib 420 mg orally once daily as monotherapy (Ibrutinib Arm) in 662 patients (including 3 Japanese patients) with chronic lymphocytic leukemia and small lymphocytic lymphoma who were untreated or had received prior therapy other than BTK inhibitors. The primary endpoint was overall response rate by central assessment.
Based on the alliance agreement concluded in March 2024, Eli Lilly Japan will be responsible for supply of Jaypirca in Japan, while Nippon Shinyaku will be responsible for distribution and sales, as well as information provision activities.

Summary of Product Information

Brand name	Jaypirca® 50 mg tablet, Jaypirca® 100 mg tablet
Generic name	Pirtobrutinib
Indications	① Relapsed or refractory mantle cell lymphoma resistant or intolerant to other BTK inhibitors ② Chronic lymphocytic leukemia (including small lymphocytic lymphoma)
Dosage and administration	In adult patients, the recommended dosage is pirtobrutinib 200 mg orally once daily. Reduce the dose accordingly based on the patient’s condition.
Date of marketing approval	June 24, 2024

Date of NHI price listing	August 15, 2024		
Launch date	August 21, 2024		
NHI price	Jaypirca® 50 mg tablet Jaypirca® 100 mg tablet	Per 50 mg tablet Per 100 mg tablet	JPY 10,201.00 JPY 19,465.80
Manufacturer	Eli Lilly Japan K.K.		
Distributor	Nippon Shinyaku Co., Ltd.		

Product Images



Jaypirca® 50 mg tablet



Jaypirca® 100 mg tablet

Global Phase 3 Randomized Controlled Study (BRUIN-CLL-313 Study)

The BRUIN-CLL-313 study compared pirtobrutinib 200 mg orally once daily as monotherapy (Pirtobrutinib Arm) with bendamustine plus rituximab※2 (BR Arm) in 282 patients (including 12 Japanese patients) with untreated chronic lymphocytic leukemia and small lymphocytic lymphoma※1. Progression-free survival by central assessment, the primary endpoint, is shown in the table below; a statistically significant extension was observed in the Pirtobrutinib Arm compared with the BR Arm.

※1) Patients without chromosome 17p deletion were included

※2) One cycle is 28 days. Bendamustine hydrochloride 90 mg/m^2 was administered intravenously on Days 1 and 2 of Cycles 1–6. Rituximab (genetic recombination) 375 mg/m^2 was administered on Day 1 of Cycle 1, followed by 500 mg/m^2 intravenously on Day 1 of Cycles 2–6

Results of the Global Phase 3 Randomized Controlled Study (BRUIN-CLL-313 Study)

	Pirtobrutinib Arm	BR Arm
Number of patients (Number of Japanese patients)	141(4)	141(8)
Number of events	13	48
Median progression-free survival (months) (95% CI)	Not reached (Not estimable-Not estimable)	33.54 (32.72-Not estimable)
Hazard ratio[a] (95% CI)	0.199 (0.107-0.367)	
Two-sided p-value[b]	P<0.0001	

a) Calculated by stratified Cox proportional hazards model

b) Stratified log-rank test (significance level: 0.05, two-sided)

Adverse drug reactions were observed in 83 (59.3%) of the 140 patients (including 4 Japanese patients) in the Pirtobrutinib Arm in the safety analysis population. The most common adverse drug reactions in the Pirtobrutinib Arm were neutropenia (10.7%), hypertension (5.0%), urinary tract infection (5.0%), contusion (4.3%), and petechiae (4.3%).

Global Phase 3 Study (BRUIN-CLL-314 Study)

The BRUIN-CLL-314 study was an open-label, randomized Phase 3 study comparing pirtobrutinib 200 mg orally once daily as monotherapy (Pirtobrutinib Arm) with ibrutinib 420 mg orally once daily as monotherapy (Ibrutinib Arm) in 662 patients (including 3 Japanese patients) with chronic lymphocytic leukemia and small lymphocytic lymphoma who were untreated or had received prior therapy other than BTK inhibitors※3. The primary endpoint, overall response rate (ORR) by central assessment, is shown in the table below.

※3) Patients previously treated with BTK inhibitors were excluded from enrollment

Results of the Global Phase 3 Randomized Controlled Study (BRUIN-CLL-314 Study)

	ITT population		Pretreated population	
	Pirtobrutinib Arm	Ibrutinib Arm	Pirtobrutinib Arm	Ibrutinib Arm
Number of patients (Number of Japanese patients)	331(3)	331(0)	219(2)	218(0)
Number of events	288	260	184	163
ORR (%) (95% CI)	87.01 (82.90-90.44)	78.55 (73.73-82.85)	84.02 (78.48-88.61)	74.77 (68.46-80.39)
ORR ratio (95% CI)	1.108 (1.034-1.187)[b)]		1.123 (1.020-1.237)[c)]	
One-sided p-value[a)]	P<0.0001[d)]		P<0.0001[e)]	

a) Wald test stratified by randomization factors, with a non-inferiority margin of 0.88 in the ITT population and 0.86 in the pretreated population (significance level: 0.05, two-sided)
b) The 99.5% confidence interval corresponding to the significance level was (1.004-1.223)
c) The 95.5% confidence interval corresponding to the significance level was (1.018-1.240)
d) Significance level (one-sided): 0.0025
e) Significance level (one-sided): 0.0225

Adverse drug reactions were observed in 254 (77.0%) of the 330 patients (including 3 Japanese patients) in the Pirtobrutinib Arm in the safety analysis population. The most common adverse drug reactions in the Pirtobrutinib Arm were neutropenia (20.0%), anemia (9.7%), contusion (8.5%), neutrophil count decreased (6.7%), and pneumonia (6.7%).

About Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL)

CLL and SLL are both tumors that arise from lymphocytes, a type of white blood cell, and are slowly progressing diseases[i,ii]. In Japan, CLL and SLL are rare diseases, and the total numbers of patients are estimated at 7,000 and 4,000, respectively[iii]. CLL and SLL share the same pathological features and immunophenotype but differ in where the cancer cells are located in the body[i]. In CLL, the cancer cells are found in the blood, whereas in SLL, the cancer cells are found in the lymph nodes[i].

i. Mukkamalla SKR, Taneja A, Malipeddi D, et al. Chronic Lymphocytic Leukemia. [Updated 2023 Feb 18]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan. Available from: https://www.ncbi.nlm.nih.gov/books/NBK470433/
ii. The Leukemia and Lymphoma Society. NHL Subtypes. Access here: https://bloodcancerunited.org/blood-cancer/lymphoma/non-hodgkin-lymphoma-nhl. Accessed on October 25, 2023.
iii. Government statistics: Patient Survey, FY2023 (Reiwa 5)

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 is the Japanese subsidiary of Eli Lilly and Company based in the United States. We have been developing and supplying world-class, innovative medicines by uniting caring with discovery for 50 years to help patients in Japan achieve healthier and more fulfilling lives. We currently contribute to Japanese medicine in multiple areas, including cancer, diabetes, Alzheimer's disease and other central nervous system diseases, as well as autoimmune diseases, etc. For more details, please visit our website.

https://www.lilly.com/jp

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