Jaypirca® (pirtobrutinib) Now Approved by U.S. FDA for the Treatment of Adult Patients with Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma Who Have Received at Least Two Lines of Therapy, Including a BTK Inhibitor and a BCL-2 Inhibitor

December 1, 2023

The first and only non-covalent (reversible) BTK inhibitor, Jaypirca has been shown to extend the benefit of BTK inhibition

In the BRUIN Phase 1/2 trial, adult patients with CLL/SLL who have received at least two lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor, achieved an overall response rate of 72%

INDIANAPOLIS, Dec. 1, 2023 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the U.S. Food and Drug Administration (FDA) approved Jaypirca® (pirtobrutinib, 100 mg & 50 mg tablets) for the treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have received at least two prior lines of therapy, including a Bruton's tyrosine kinase (BTK) inhibitor and a BCL-2 inhibitor. Jaypirca was approved under the FDA's Accelerated Approval pathway based on overall response rate (ORR) and duration of response (DOR) from the open-label, single-arm, multicohort, international, Phase 1/2 BRUIN trial.[1] Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.[1]

Jaypirca, the first and only FDA-approved non-covalent (reversible) BTK inhibitor, is a highly selective kinase inhibitor that can extend the benefit of targeting the BTK pathway in CLL/SLL patients previously treated with a covalent BTK inhibitor (ibrutinib, acalabrutinib, or zanubrutinib) and a BCL-2 inhibitor.[1,2] Jaypirca utilizes a novel binding mechanism and has the largest body of evidence of any targeted therapy in patients previously treated with a BTK inhibitor.[1,2]

"Once patients with CLL or SLL have progressed on covalent BTK inhibitor and BCL-2 inhibitor therapies, treatments are limited and outcomes can be poor, making the approval of Jaypirca a meaningful advance and much-needed new treatment option for these patients," said William G. Wierda, M.D., Ph.D., professor, medical director, and CLL section head for the Department of Leukemia at The University of Texas MD Anderson Cancer Center. "Jaypirca offers a new treatment option and different approach to targeting BTK, providing clinical benefit for a high proportion of patients with CLL or SLL in the BRUIN Phase 1/2 trial whose disease progressed following treatment with a covalent BTK inhibitor and with a BCL-2 inhibitor."

The labeling for Jaypirca contains warnings and precautions for infections, hemorrhage, cytopenias, cardiac arrhythmias, second primary malignancies, and embryo-fetal toxicity. See Important Safety Information below and full Prescribing Information for additional information, including dosing modifications.

"This FDA approval — the second for Jaypirca in 2023 — underscores the impactful clinical benefit of continuing to leverage the BTK pathway with Jaypirca for patients with CLL or SLL as seen in the BRUIN trial," said Jacob Van Naarden, chief executive officer, Loxo@Lilly. "These first two indications for Jaypirca represent the beginning of the eventual impact that we hope Jaypirca can have for patients, and we look forward to seeing the results of the comprehensive Phase 3 development program across CLL, SLL and MCL."

"The treatment landscape for CLL has been dramatically improved by the introduction of covalent BTK inhibitors and BCL-2 inhibitors. However, most patients will unfortunately relapse eventually," said Brian Koffman, M.D., chief medical officer and executive vice president at the CLL Society. "Pirtobrutinib's approval gives patients a much-needed option and brings forward new possibilities as they continue their treatment journey."

The FDA approval is based on data from a subset of patients in the BRUIN Phase 1/2 trial. The assessment of efficacy was based on 108 patients with CLL/SLL treated with Jaypirca who were previously treated with at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor. Jaypirca 200 mg was given once daily and was continued until disease progression or unacceptable toxicity. Patients with active central nervous system (CNS) involvement by lymphoma or allogeneic hematopoietic stem cell transplantation (HSCT) within 60 days were excluded. Patients in the efficacy-eligible population had received a median of five prior lines of therapy (range: 2 to 11). The most common prior BTK inhibitors received were ibrutinib (97%), acalabrutinib (9%), and zanubrutinib (0.9%). Seventy-seven percent (77%) of patients discontinued the last BTK inhibitor for refractory or progressive disease. Efficacy was established based on ORR and DOR, as assessed by an independent review committee (IRC) using 2018 International Workshop on Chronic Lymphocytic Leukemia (iwCLL) criteria. Efficacy results are summarized below:

Outcome	**Jaypirca 200 mg once daily (N=108)**
Overall Response Rate	
ORR, n (95% CI, %)	78 (72 %) 63, 80
PR, n	78 (72 %)
Time to Response Median (range), months	3.7 (1.7, 27.9)
Duration of Response[a]	
Median DOR, months (95% CI)	12.2 (9.3, 14.7)

CI, confidence interval; PR, partial response.

[a] Based on Kaplan-Meier estimation. Estimated median follow-up was 15.7 months.

The pooled safety analysis of the full BRUIN study population evaluated 593 patients with hematologic malignancies administered Jaypirca 200 mg daily as a single agent. In this pooled safety population, the most common adverse reactions (ARs) to Jaypirca therapy, occurring in 20% of patients or more, including laboratory abnormalities, were decreased neutrophil count, decreased hemoglobin, fatigue, decreased lymphocyte count, musculoskeletal pain, decreased platelet count, diarrhea, COVID-19, bruising, and cough.

The safety of Jaypirca was evaluated in the BRUIN trial in 110 patients with CLL/SLL, with 98% receiving at least two prior lines of systemic therapy, including a BTK inhibitor and a BCL-2 inhibitor. Sixty percent (60%) of these patients were exposed to Jaypirca for at least one year, and 14% were exposed for at least two years. ARs led to dose reductions in 3.6%, treatment interruption in 42%, and permanent discontinuation of Jaypirca in 9% of patients. ARs that resulted in permanent discontinuation of Jaypirca in more than 1% of patients included second primary malignancy, COVID-19, and sepsis. Serious ARs occurred in 56% of patients who received Jaypirca. Serious ARs occurring in greater than or equal to 5% of patients were pneumonia (18%), COVID-19 (9%), sepsis (7%), and febrile neutropenia (7%).

Lilly is committed to delivering on the requirements of the FDA's Accelerated Approval pathway, including the completion of confirmatory studies supporting traditional approval as soon as possible. The Phase 3 randomized confirmatory trial intended to convert this approval to traditional approval is BRUIN CLL-321, which reached its target number of progression-free survival (PFS) events and met its primary endpoint. Topline results were shared with the FDA in November 2023, although these data have not yet been formally reviewed. BRUIN CLL-321 is a randomized Phase 3 trial comparing pirtobrutinib monotherapy versus the investigator's choice of either idelalisib in combination with rituximab or bendamustine in combination with rituximab in patients with CLL/SLL who have been treated with at least a BTK inhibitor. These data will be presented at an upcoming medical meeting. Jaypirca is not approved for use in the BRUIN CLL-321 population.

This is the second FDA-approved indication for Jaypirca following the January 2023 Accelerated Approval for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor.

Loxo@Lilly is studying Jaypirca in CLL/SLL in multiple Phase 3 studies. Details on the trials can be found by visiting clinicaltrials.gov.

See Important Safety Information below and full Prescribing Information for additional information.

Click here to view the CLL infographic.

Click to view the Jaypirca product photos: 100 mg and 50 mg.

Click here to view the Jaypirca logo.

About the BRUIN Phase 1/2 Trial
The BRUIN Phase 1/2 clinical trial is the ongoing first-in-human, global, multi-center evaluation of Jaypirca in patients with hematologic malignancies, including chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), and mantle cell lymphoma (MCL).

The trial includes a Phase 1 dose-escalation phase, a Phase 1b combination arm, and a Phase 2 dose-expansion phase. The primary endpoint of the Phase 1 study is maximum tolerated dose (MTD)/recommended Phase 2 dose (RP2D). Secondary endpoints include safety, pharmacokinetics (PK), and preliminary efficacy measured by overall response rate (ORR) for monotherapy. The primary endpoint of the Phase 1b study is safety of the drug combinations. The secondary endpoints are PK and preliminary efficacy measured by ORR for the drug combinations. The primary endpoint for the Phase 2 study is ORR as determined by an independent review committee (IRC). Secondary endpoints include ORR as determined by investigator, best overall response (BOR), duration of response (DOR), progression-free survival (PFS), overall survival (OS), safety, and PK.

About Jaypirca® (pirtobrutinib)
Jaypirca (pirtobrutinib, formerly known as LOXO-305) (pronounced jay-pihr-kaa) is a highly selective (300 times more selective for BTK versus 98% of other kinases tested in preclinical studies), non-covalent (reversible) inhibitor of the enzyme BTK.[2] BTK is a validated molecular target found across numerous B-cell leukemias and lymphomas including mantle cell lymphoma and chronic lymphocytic leukemia/small lymphocytic lymphoma.[3,4] Jaypirca is a U.S. FDA-approved oral prescription medicine, 100 mg or 50 mg tablets taken as a once-daily 200 mg dose with or without food until disease progression or unacceptable toxicity.

About Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
CLL and SLL are forms of slow-growing non-Hodgkin lymphoma that develop from white blood cells known as lymphocytes.[5,6] CLL is one of the most common types of leukemia in adults.[5] In the U.S., CLL accounts for about one-quarter of the new cases of leukemia and there are approximately 18,740 new cases of CLL diagnosed this year.[5,7] SLL is identical to CLL from a pathologic and immunophenotypic standpoint, with the main difference between them being the location of the cancer cells.[5] In CLL, the cancer cells are present in the blood, and in SLL, the cancer cells are found in the lymph nodes.[5]

INDICATIONS FOR JAYPIRCA
Jaypirca is a kinase inhibitor indicated for the treatment of

- Adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor.
- Adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor.

These indications are approved under accelerated approval based on response rate. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial.

IMPORTANT SAFETY INFORMATION FOR JAYPIRCA® (pirtobrutinib)

Infections: Fatal and serious infections (including bacterial, viral, fungal) and opportunistic infections occurred in Jaypirca-treated patients. In a clinical trial, Grade ≥3 infections occurred in 24% of patients with hematologic malignancies, most commonly pneumonia (14%); fatal infections occurred in

4.4%. Sepsis (6%) and febrile neutropenia (4%) occurred. In patients with CLL/SLL, Grade ≥3 infections occurred (32%), with fatal infections occurring in 8%. Opportunistic infections included *Pneumocystis jirovecii* pneumonia and fungal infection. Consider prophylaxis, including vaccinations and antimicrobial prophylaxis, in patients at increased risk for infection, including opportunistic infections. Monitor patients for signs and symptoms, evaluate promptly, and treat appropriately. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca.

Hemorrhage: Fatal and serious hemorrhage has occurred with Jaypirca. Major hemorrhage (Grade ≥3 bleeding or any central nervous system bleeding) occurred in 3% of patients, including gastrointestinal hemorrhage; fatal hemorrhage occurred (0.3%). Bleeding of any grade, excluding bruising and petechiae, occurred in 17%. Major hemorrhage occurred in patients taking Jaypirca with (0.7%) and without (2.3%) antithrombotic agents. Consider risks/benefits of co-administering antithrombotic agents with Jaypirca. Monitor patients for signs of bleeding. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca. Consider benefit/risk of withholding Jaypirca 3-7 days pre- and post-surgery depending on type of surgery and bleeding risk.

Cytopenias: Jaypirca can cause cytopenias, including neutropenia, thrombocytopenia, and anemia. In a clinical trial, Grade 3 or 4 cytopenias, including decreased neutrophils (26%), decreased platelets (12%), and decreased hemoglobin (12%), developed in Jaypirca-treated patients. Grade 4 decreased neutrophils (14%) and Grade 4 decreased platelets (6%) developed. Monitor complete blood counts regularly during treatment. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca.

Cardiac Arrhythmias: Cardiac arrhythmias occurred in patients who received Jaypirca. In a clinical trial of patients with hematologic malignancies, atrial fibrillation or flutter were reported in 3.2% of Jaypirca-treated patients, with Grade 3 or 4 atrial fibrillation or flutter in 1.5%. Other serious cardiac arrhythmias such as supraventricular tachycardia and cardiac arrest occurred (0.5%). Patients with cardiac risk factors such as hypertension or previous arrhythmias may be at increased risk. Monitor for signs and symptoms of arrhythmias (e.g., palpitations, dizziness, syncope, dyspnea) and manage appropriately. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca.

Second Primary Malignancies: Second primary malignancies, including non-skin carcinomas, developed in 9% of Jaypirca-treated patients. The most frequent malignancy was non-melanoma skin cancer (4.6%). Other second primary malignancies included solid tumors (including genitourinary and breast cancers) and melanoma. Advise patients to use sun protection and monitor for development of second primary malignancies.

Embryo-Fetal Toxicity: Jaypirca can cause fetal harm in pregnant women. Administration of pirtobrutinib to pregnant rats during organogenesis caused embryo-fetal toxicity, including embryo-fetal mortality and malformations at maternal exposures (AUC) approximately 3-times the recommended 200 mg/day dose. Advise pregnant women of potential fetal risk and females of reproductive potential to use effective contraception during treatment and for one week after last dose.

Adverse Reactions (ARs) in Patients Who Received Jaypirca

The most common (≥20%) ARs in the BRUIN pooled safety population of patients with hematologic malignancies (n=593) were decreased neutrophil count (46%), decreased hemoglobin (39%), fatigue (32%), decreased lymphocyte count (31%), musculoskeletal pain (30%), decreased platelet count (29%), diarrhea (24%), COVID-19 (22%), bruising (21%), cough (20%).

Mantle Cell Lymphoma

Serious ARs occurred in 38% of patients. Serious ARs occurring in ≥2% of patients were pneumonia (14%), COVID-19 (4.7%), musculoskeletal pain (3.9%), hemorrhage (2.3%), pleural effusion (2.3%), and sepsis (2.3%). **Fatal ARs** within 28 days of last Jaypirca dose occurred in 7% of patients, most commonly due to infections (4.7%), including COVID-19 (3.1% of all patients).

Dose Modifications and Discontinuations: ARs led to dose reductions in 4.7%, treatment interruption in 32%, and permanent discontinuation of Jaypirca in 9% of patients. ARs resulting in dosage modification in >5% of patients included pneumonia and neutropenia. ARs resulting in permanent discontinuation in >1% of patients included pneumonia.

ARs (all Grades %; Grade 3-4 %) in ≥10% of Patients: fatigue (29; 1.6), musculoskeletal pain (27; 3.9), diarrhea (19; -), edema (18; 0.8), dyspnea (17; 2.3), pneumonia (16; 14), bruising (16; -), peripheral neuropathy (14; 0.8), cough (14; -), rash (14; -), fever (13; -), constipation (13; -), arthritis/arthralgia (12; 0.8), hemorrhage (11; 3.1), abdominal pain (11; 0.8), nausea (11; -), upper respiratory tract infections (10; 0.8), dizziness (10; -).

Select Laboratory Abnormalities (all Grades %; Grade 3 or 4 %) that Worsened from Baseline in ≥10% of Patients: hemoglobin decreased (42; 9), platelet count decreased (39; 14), neutrophil count decreased (36; 16), lymphocyte count decreased (32; 15), creatinine increased (30; 1.6), calcium decreased (19; 1.6), AST increased (17; 1.6), potassium decreased (13; 1.6), sodium decreased (13; -), lipase increased (12; 4.4), alkaline phosphatase increased (11; -), ALT increased (11; 1.6), potassium increased (11; 0.8). Grade 4 laboratory abnormalities in >5% of patients included neutrophils decreased (10), platelets decreased (7), lymphocytes decreased (6).

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

Serious ARs occurred in 56% of patients. Serious ARs occurring in ≥5% of patients were pneumonia (18%), COVID-19 (9%), sepsis (7%), and febrile neutropenia (7%). **Fatal ARs** within 28 days of last Jaypirca dose occurred in 11% of patients, most commonly due to infections (10%), including sepsis (5%) and COVID-19 (2.7%).

Dose Modifications and Discontinuations: ARs led to dose reductions in 3.6%, treatment interruption in 42%, and permanent discontinuation of Jaypirca in 9% of patients. ARs resulting in dose reductions in >1% included neutropenia; treatment interruptions in >5% of patients included pneumonia, neutropenia, febrile neutropenia, and COVID-19; permanent discontinuation in >1% of patients included second primary malignancy, COVID-19, and sepsis.

ARs (all Grades %; Grade 3-4 %) in ≥10% of Patients: fatigue (36; 2.7), bruising (36; -), cough (33; -), musculoskeletal pain (32; 0.9), COVID-19 (28; 7), pneumonia (27; 16), diarrhea (26; -), abdominal pain (25; 2.7), dyspnea (22; 2.7), hemorrhage (22; 2.7), edema (21; -), nausea (21; -), pyrexia (20; 2.7), headache (20; 0.9), arthritis/arthralgia (19; 1.8), rash (19; 0.9), peripheral neuropathy (16; 3.6), dizziness (15; -), fall (14; 0.9), constipation (14; -), insomnia (14; -), upper respiratory tract infections (13; 2.7), second primary malignancy (13; 2.7), renal insufficiency (12; 6), hypertension (12; 5), neurological changes (12; 2.7), mucositis (12; 0.9), decreased appetite (12; -), respiratory tract infection (11; 1.8), supraventricular tachycardia (10; 5).

Select Laboratory Abnormalities (all Grades %; Grade 3 or 4 %) that Worsened from Baseline in ≥20% of Patients: neutrophil count

decreased (63; 45), hemoglobin decreased (48; 19), calcium decreased (40; 2.8), platelet count decreased (30; 15), sodium decreased (30; -), lymphocyte count decreased (23; 8), ALT increased (23; 2.8), AST increased (23; 1.9), creatinine increased (23; -), lipase increased (21; 7), alkaline phosphatase increased (21; -). Grade 4 laboratory abnormalities in >5% of patients included neutrophils decreased (23).

Drug Interactions

Strong CYP3A Inhibitors: Concomitant use with Jaypirca increased pirtobrutinib systemic exposure, which may increase risk of Jaypirca ARs. Avoid use of strong CYP3A inhibitors with Jaypirca. If concomitant use is unavoidable, reduce Jaypirca dosage according to approved labeling.

Strong or Moderate CYP3A Inducers: Concomitant use with Jaypirca decreased pirtobrutinib systemic exposure, which may reduce Jaypirca efficacy. Avoid concomitant use of Jaypirca with strong or moderate CYP3A inducers. If concomitant use with moderate CYP3A inducers is unavoidable, increase Jaypirca dosage according to approved labeling.

Sensitive CYP2C8, CYP2C19, CYP3A, P-gp, or BCRP Substrates: Concomitant use with Jaypirca increased their plasma concentrations, which may increase risk of adverse reactions related to these substrates for drugs that are sensitive to minimal concentration changes. Follow recommendations for these sensitive substrates in their approved labeling.

Use in Special Populations

Pregnancy and Lactation: Due to potential for Jaypirca to cause fetal harm, verify pregnancy status in females of reproductive potential prior to starting Jaypirca and advise use of effective contraception during treatment and for one week after last dose. Presence of pirtobrutinib in human milk is unknown. Advise women not to breastfeed while taking Jaypirca and for one week after last dose.

Geriatric Use: In the pooled safety population of patients with hematologic malignancies, patients aged ≥65 years experienced higher rates of Grade ≥3 ARs and serious ARs compared to patients <65 years of age.

Renal Impairment: Severe renal impairment increases pirtobrutinib exposure. Reduce Jaypirca dosage in patients with severe renal impairment according to approved labeling.

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Please see Prescribing Information and Patient Information for Jaypirca.

About Lilly
Lilly unites caring with discovery to create medicines that make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help more than 51 million people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges, redefining diabetes care, treating obesity and curtailing its most devastating long-term effects, advancing the fight against Alzheimer's disease, providing solutions to some of the most debilitating immune system disorders, and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/newsroom or follow us on Facebook, Instagram and LinkedIn. P-LLY

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Lilly Cautionary Statement Regarding Forward-Looking Statements
This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Jaypirca® as a treatment for adult patients with mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor, and as a treatment for adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there is no guarantee that planned or ongoing studies will be completed as planned, that future study results will be consistent with study results to date, that Jaypirca will receive additional regulatory approvals, or that Jaypirca will be commercially successful. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, see Lilly's Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

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