



Lilly to spotlight growing hematology portfolio at 2026 European Hematology Association (EHA) Annual Meeting

June 2, 2026

Positive results from the Phase 3 BRUIN CLL-322 study comparing time-limited pirtobrutinib plus venetoclax and rituximab versus venetoclax and rituximab in patients with relapsed or refractory CLL/SLL will be highlighted in a late-breaking oral presentation

Ajax Therapeutics, which Lilly has agreed to acquire, will present the first clinical data for its first-in-class type II JAK2 inhibitor for patients with myelofibrosis who have been failed by a type I JAK2 inhibitor

Kelonia Therapeutics, which Lilly has agreed to acquire, will present additional correlative clinical data for its in vivo CAR-T program in patients with multiple myeloma

INDIANAPOLIS, June 2, 2026 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced the details of presentations at the European Hematology Association (EHA) Annual Meeting, taking place June 11-14 in Stockholm, Sweden.

Data to be highlighted include an oral presentation detailing results from the Phase 3 BRUIN CLL-322 study of Jaypirca (pirtobrutinib), a non-covalent Bruton tyrosine kinase (BTK) inhibitor, as part of a time-limited regimen for patients with previously treated chronic lymphocytic leukemia (CLL). Lilly is strengthening its hematology portfolio through the recently announced proposed acquisitions of Ajax Therapeutics, Inc.* and Kelonia Therapeutics, Inc.*, each of which will present data at the meeting. Ajax Therapeutics will present the first clinical data from the Phase 1 AJX-101 study evaluating AJ1-11095, an investigational first-in-class type II JAK2 inhibitor, in patients with myelofibrosis who have been failed by a type I JAK2 inhibitor. Kelonia Therapeutics will present additional correlative data from the Phase 1 inMMycAR study of an investigational anti-B-cell maturation antigen (BCMA) targeted in vivo CAR-T therapy in patients with relapsed and refractory multiple myeloma. Both proposed acquisitions by Lilly are pending transaction closes.

"These data at EHA represent a significant moment for Lilly's hematology ambitions," said Jacob Van Naarden, executive vice president and president of Lilly Oncology. "The Phase 3 BRUIN CLL-322 results address an important question for patients with relapsed or refractory CLL, demonstrating that time-limited pirtobrutinib can meaningfully improve outcomes when added to an already effective venetoclax-based regimen. Alongside the first clinical data from Ajax and additional results from Kelonia in support of the recently presented data at ASCO, these results reflect our relentless commitment to pursue meaningful advancements for people living with blood disorders."

Presentation Highlights:

Lilly:

- In a late-breaking oral presentation, Lilly will share results from the Phase 3 BRUIN CLL-322 study, evaluating a time-limited regimen of pirtobrutinib plus venetoclax and rituximab versus venetoclax and rituximab in patients with relapsed or refractory CLL/SLL. BRUIN CLL-322 is the first Phase 3 readout in CLL to outperform a venetoclax-containing control arm in any CLL setting. Lilly previously announced that the study met its primary endpoint, demonstrating that the addition of pirtobrutinib to venetoclax plus rituximab led to a statistically significant and clinically meaningful improvement in progression-free survival (PFS). These results were also selected to be featured in the EHA press program.

Ajax Therapeutics:

- In an oral presentation, Ajax will share the first clinical results from the Phase 1 AJX-101 clinical trial, evaluating AJ1-11095, an investigational first-in-class type II JAK2 inhibitor, in patients with myelofibrosis who have been failed by a type I JAK2 inhibitor. These data will also be featured in the EHA press program.

Kelonia Therapeutics:

- In an oral presentation, Kelonia will share additional correlative data from the Phase 1 inMMycAR dose-escalation study, evaluating KLN-1010 in relapsed or refractory multiple myeloma. [Data](#) from this study were recently shared at the American Society of Clinical Oncology (ASCO) Annual Meeting.

A full list of abstract titles and viewing details are listed below:

Abstract Title	Author	Presentation Type/#	Session Title	Session Date/Time (CEST)
Jaypirca (pirtobrutinib; non-covalent BTK inhibitor)				

Fixed-duration pirtobrutinib plus venetoclax–rituximab versus venetoclax–rituximab for patients with previously treated CLL/SLL: A phase 3, randomized study (BRUIN CLL-322)	Matthew Davids	Oral #LB5001	Late-breaking oral session	Sunday, June 14 9:15 – 10:45
Pirtobrutinib in treatment-naïve patients with CLL/SLL: Pooled results from BRUIN CLL-313 and BRUIN CLL-314	Jennifer Woyach	Poster #PS1701	Chronic lymphocytic leukemia and related disorders - Clinical	Saturday, June 13 18:45 – 19:45
Patient-reported outcomes of pirtobrutinib vs. bendaR in untreated CLL/SLL: Findings from BRUIN-CLL-313 Phase 3 study	Tomasz Wrobel	Poster #PF1386	Quality of life, ethics, supportive and palliative care	Friday, June 12 18:45 – 19:45
Investigator Initiated A Phase 2 study of fixed-duration pirtobrutinib and obinutuzumab in previously untreated CLL	Inhye E. Ann	Oral Session #S148	Prognostication and first line therapy in CLL	Friday, June 12 18:00 – 18:15
AJ1-11095 (Ajax's investigational first-in-class type II JAK2 inhibitor)				
Results of AJX-101, a Phase 1 clinical trial of the type II JAK2 inhibitor AJ1-11095, in patients with myelofibrosis who have been failed by a type I JAK2 inhibitor	John Mascarehas	Oral Session #S218	Myeloproliferative neoplasms - Clinical	Saturday, June 13 18:00 – 18:15
KLN-1010 (Kelsonia's investigational in vivo CAR-T therapy)				
Successful in vivo CAR-T generation and minimal residual disease (MRD) clearance with KLN-1010 across diverse baseline T Cell phenotypes in relapsed/refractory multiple myeloma (RRMM)	Andrew Spencer	Oral Session #S185	T cell redirected therapy in multiple myeloma	Thursday, June 11 16:45 – 17:00

For more information on Lilly's oncology pipeline click [here](#).

*Lilly and Ajax Therapeutics, Inc., and Lilly and Kelsonia Therapeutics, Inc., remain separate, independent companies prior to closing. Both transactions are subject to customary closing conditions, including regulatory approvals, with Ajax Therapeutics expected to close in June 2026 and Kelsonia Therapeutics expected to close in the second half of 2026.

About Jaypirca (pirtobrutinib)

Jaypirca (pirtobrutinib) (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 inhibitor of the enzyme BTK.¹ BTK is a validated molecular target found across numerous B-cell leukemias and lymphomas including mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL).^{2,3} 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.

INDICATIONS FOR JAYPIRCA (pirtobrutinib)

Jaypirca is indicated for the treatment of

- Adult patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have previously been treated with a covalent BTK inhibitor.
- Adult patients with relapsed or refractory (R/R) mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor. This indication is approved under accelerated approval based on response rate. Continued approval for this indication 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. Across clinical trials, Grade ≥3 infections occurred (25%), most commonly pneumonia (20%); fatal infections (5%), sepsis (6%), and febrile neutropenia (3.8%) 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 for signs and symptoms, evaluate, and treat. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca.

Hemorrhage: Fatal and serious hemorrhage has occurred with Jaypirca. Across clinical trials, major hemorrhage (Grade ≥3 bleeding or any central nervous system bleeding) occurred (2.6%), including gastrointestinal hemorrhage; fatal hemorrhage occurred (0.3%). Bleeding of any grade, excluding bruising and petechiae, occurred (16%). Major hemorrhage occurred when taking Jaypirca with (2.0%) and without (0.6%) antithrombotic agents. Consider risks/benefits of co-administering antithrombotic agents with Jaypirca. Monitor for signs of bleeding. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca. Consider withholding Jaypirca 3-7 days pre- and post-surgery based on surgery type and bleeding risk.

Cytopenias: Jaypirca can cause cytopenias, including neutropenia, thrombocytopenia, and anemia. Across clinical trials, Grade 3 or 4 cytopenias, including decreased neutrophils (27%), decreased platelets (13%), and decreased hemoglobin (11%), developed. Grade 4 decreased neutrophils (15%) and Grade 4 decreased platelets (6%) developed. Monitor complete blood counts regularly. Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca.

Cardiac Arrhythmias: Cardiac arrhythmias occurred in patients taking Jaypirca. Across clinical trials, atrial fibrillation or flutter were reported in 3.4% of Jaypirca treated patients, with Grade 3 or 4 atrial fibrillation or flutter in 1.6%. Other serious cardiac arrhythmias such as supraventricular tachycardia and cardiac arrest occurred (0.4%). Cardiac risk factors such as hypertension or previous arrhythmias may increase risk. Monitor and manage signs and symptoms of arrhythmias (e.g., palpitations, dizziness, syncope, dyspnea). Based on severity, reduce dose, temporarily withhold, or permanently discontinue Jaypirca.

Second Primary Malignancies: Across clinical trials, second primary malignancies, including non-skin carcinomas, developed in 9% of Jaypirca-

treated patients, most frequently non-melanoma skin cancer (4.4%). 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.

Hepatotoxicity, Including Drug-Induced Liver Injury (DILI): Hepatotoxicity, including severe, life-threatening, and potentially fatal cases of DILI, has occurred in patients treated with BTK inhibitors, including Jaypirca. Evaluate bilirubin and transaminases at baseline and throughout Jaypirca treatment. For patients who develop abnormal liver tests after Jaypirca, monitor more frequently for liver test abnormalities and clinical signs and symptoms of hepatic toxicity. If DILI is suspected, withhold Jaypirca. If DILI is confirmed, discontinue Jaypirca.

Embryo-Fetal Toxicity: Jaypirca can cause fetal harm. Administration of pirtobrutinib to pregnant rats 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 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 ($\geq 30\%$) ARs in the pooled safety population of patients with hematologic malignancies (n=704) were decreased neutrophil count (54%), decreased hemoglobin (43%), decreased leukocytes (32%), fatigue (31%), decreased platelets (31%), decreased lymphocyte count (31%), calcium decreased (30%).

Mantle Cell Lymphoma

Serious ARs occurred in 38% of patients, with pneumonia (14%), COVID-19 (4.7%), musculoskeletal pain (3.9%), hemorrhage (2.3%), pleural effusion (2.3%), and sepsis (2.3%) occurring in $\geq 2\%$ of patients. **Fatal ARs** within 28 days of last 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 Due to ARs: Dose reductions in 4.7%, treatment interruption in 32%, and permanent discontinuation of Jaypirca in 9% of patients. Permanent discontinuation in $>1\%$ of patients included pneumonia.

Most common ARs ($\geq 15\%$) and Select Laboratory Abnormalities ($\geq 10\%$) (all Grades %; Grade 3-4 %): hemoglobin decreased (42; 9), platelet count decreased (39; 14), neutrophil count decreased (36; 16), lymphocyte count decreased (32; 15), creatinine increased (30; 1.6), fatigue (29; 1.6), musculoskeletal pain (27; 3.9), calcium decreased (19; 1.6), diarrhea (19; -), edema (18; 0.8), dyspnea (17; 2.3), AST increased (17; 1.6), pneumonia (16; 14), bruising (16; -), potassium decreased (13; 1.6), sodium decreased (13; -), lipase increased (12; 4.4), ALT increased (11; 1.6), potassium increased (11; 0.8), alkaline phosphatase increased (11; -). Grade 4 laboratory abnormalities in $>5\%$ of patients included neutrophils decreased (10), platelets decreased (7), lymphocytes decreased (6).

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma from Single-Arm and Randomized Controlled Clinical Trials

Serious ARs occurred in 47-56% of patients across clinical trials. Serious ARs in $\geq 5\%$ of patients in the single-arm trial were pneumonia (18%), COVID-19 (9%), sepsis (7%), febrile neutropenia (7%). Serious ARs in $\geq 3\%$ of patients in the randomized controlled trial were pneumonia (21%), COVID-19 (5%), sepsis (3.4%). **Fatal ARs** within 28-30 days of last Jaypirca dose occurred in 8-11% of patients, most commonly due to infections (7-10%), including sepsis (5%), COVID-19 (2.7-5%), and pneumonia (3.4%).

Dose Modifications and Discontinuations Due to ARs: Dose reductions in 3.6-10%, treatment interruption in 42-51%, and permanent discontinuation of Jaypirca in 9-17% of patients. Permanent discontinuation in $>1\%$ of patients included second primary malignancy, pneumonia, COVID-19, neutropenia, sepsis, anemia, and cardiac arrhythmias.

Most common ARs and Select Laboratory Abnormalities ($\geq 20\%$) (all Grades %, Grade 3-4 %)--in a randomized controlled trial: neutrophil count decreased (54; 26), hemoglobin decreased (45; 10), platelet count decreased (37; 17), pneumonia (28; 16), ALT increased (25; 1.8), creatinine increased (25; -), calcium decreased (23; 0.9), sodium decreased (22; 0.9), bilirubin increased (21; 0.9), upper respiratory tract infections (21; 0.9); **in a single-arm trial:** neutrophil count decreased (63; 45), hemoglobin decreased (48; 19), calcium decreased (40; 2.8), fatigue (36; 2.7), bruising (36; -), cough (33; -), musculoskeletal pain (32; 0.9), platelet count decreased (30; 15), sodium decreased (30; -), COVID-19 (28; 7), pneumonia (27; 16), diarrhea (26; -), abdominal pain (25; 2.7), lymphocyte count decreased (23; 8), ALT increased (23; 2.8), AST increased (23; 1.9), creatinine increased (23; -), dyspnea (22; 2.7), hemorrhage (22; 2.7), lipase increased (21; 7), alkaline phosphatase increased (21; -), edema (21; -), nausea (21; -), pyrexia (20; 2.7), headache (20; 0.9). Grade 4 laboratory abnormalities in $>5\%$ of patients included neutrophils decreased (23).

Drug Interactions

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

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

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

Use in Specific 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. Presence of pirtobrutinib in human milk is unknown. Advise women to use effective contraception and to not 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: Because severe renal impairment increases pirtobrutinib exposure, reduce Jaypirca dose in these patients according to approved

labeling.

PT HCP ISI MCL_CLL Q42025

Please see [Prescribing Information](#) and [Patient Information](#) for Jaypirca.

About Lilly

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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 (pirtobrutinib), as a potential treatment for adults with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL), and the timeline for future regulatory submissions, presentations, and other milestones relating to Jaypirca and its clinical trials, 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, or that Jaypirca will receive additional regulatory approvals. 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.

Endnotes & References

1. Mato AR, Shah NN, Jurczak W, et al. Pirtobrutinib in relapsed or refractory B-cell malignancies (BRUIN): a Phase 1/2 study. *Lancet*. 2021;397(10277):892-901. doi:10.1016/S0140-6736(21)00224-5
2. Hanel W, Epperla N. Emerging therapies in mantle cell lymphoma. *J Hematol Oncol*. 2020;13(1):79. Published 2020 Jun 17. doi:10.1186/s13045-020-00914-1
3. Gu D, Tang H, Wu J, Li J, Miao Y. Targeting Bruton tyrosine kinase using non-covalent inhibitors in B cell malignancies. *J Hematol Oncol*. 2021;14(1):40. Published 2021 Mar 6. doi:10.1186/s13045-021-01049-7

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