Loxo@Lilly Announces Details of Presentations at the 2022 American Society of Hematology Annual Meeting

November 3, 2022

INDIANAPOLIS, Nov. 3, 2022 /PRNewswire/ -- Loxo@Lilly, the oncology unit of Eli Lilly and Company (NYSE: LLY), today announced that study investigators will present data from the BRUIN Phase 1/2 trial of pirtobrutinib at the American Society of Hematology (ASH) Annual Meeting to be held December 10-13, 2022, in New Orleans, Louisiana, and virtually. Pirtobrutinib is an investigational, highly selective, potent, reversible inhibitor of the Bruton's tyrosine kinase (BTK).

The pirtobrutinib oral and poster presentations will provide updated clinical data from the ongoing BRUIN Phase 1/2 study in previously treated chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), mantle cell lymphoma (MCL), Richter transformation, and Waldenström macroglobulinemia. In addition, an analysis of the safety and tolerability of pirtobrutinib monotherapy in patients with relapsed or refractory B-cell malignancies who were intolerant to a prior covalent BTK inhibitor will be presented in a poster presentation. Submitted abstracts on CLL/SLL, Richter transformation, Waldenström macroglobulinemia, and intolerance to prior covalent BTK therapy utilized a January 2022 data cut-off date, and the presentations will utilize a July 2022 data cut-off date.

A list of the presentations, along with their viewing details, is shared below.

Presentation Title	**Details**
Efficacy of Pirtobrutinib, a Highly Selective, Non-Covalent (Reversible) BTK Inhibitor in Relapsed / Refractory Waldenström Macroglobulinemia: Results from the Phase 1/2 BRUIN Study	Abstract #229 Oral Session: 623. Mantle Cell, Follicular, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological III Date: Saturday, December 10, 2022 Presentation Time: 2:00 PM CT Location: Theater C Presenter: M. Lia Palomba, M.D.
Efficacy of Pirtobrutinib, a Highly Selective, Non-Covalent (Reversible) BTK Inhibitor in Richter Transformation: Results from the Phase 1/2 BRUIN Study	Abstract #347 Oral Session: 642. Chronic Lymphocytic Leukemia: Clinical and Epidemiological: Targeted Triplet Combinations and Richter's Transformation Date: Saturday, December 10, 2022 Presentation Time: 5:00 PM CT Location: R06-R09 Presenter: William G. Wierda, M.D., Ph.D.
Efficacy of Pirtobrutinib in Covalent BTK-inhibitor Pre-treated Relapsed / Refractory CLL/SLL: Additional Patients and Extended Follow-up from the Phase 1/2 BRUIN Study	Abstract #961 Oral Session: 642. Chronic Lymphocytic Leukemia: Clinical and Epidemiological: Drugs in Development and COVID-19 Date: Monday, December 12, 2022 Presentation Time: 4:30 PM CT Location: 243-245 Presenter: Anthony R. Mato, M.D.
Safety and Tolerability of Pirtobrutinib Monotherapy in Patients with B-Cell Malignancies Who Were Previously Intolerant to a Covalent BTK Inhibitor: Results from the Phase 1/2 BRUIN Study	Abstract #1797 Poster Session: 642. Chronic Lymphocytic Leukemia: Clinical and Epidemiological: Poster I Date: Saturday, December 10, 2022 Time: 5:30 PM - 7:30 PM CT Location: Hall D Presenter: Nirav N. Shah, M.D.
Efficacy of Pirtobrutinib in Covalent BTK-inhibitor Pre-treated Relapsed / Refractory Mantle Cell Lymphoma: Additional Patients and Extended Follow-up from the Phase 1/2 BRUIN Study	Abstract #4218 Poster Session: 623. Mantle Cell, Follicular, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological: Poster III Date: Monday, December 12, 2022 Time: 6:00 PM - 8:00 PM CT Location: Hall D Presenter: Michael L. Wang, M.D.

About Pirtobrutinib (LOXO-305)
Pirtobrutinib is an investigational, highly selective, reversible (non-covalent) Bruton's tyrosine kinase (BTK) inhibitor. BTK plays a key role in the B-cell

antigen receptor signaling pathway, which is required for the development, activation and survival of normal white blood cells, known as B-cells, and malignant B-cells. BTK is a validated molecular target found across numerous B-cell leukemias and lymphomas including chronic lymphocytic leukemia (CLL), mantle cell lymphoma (MCL), and Waldenström macroglobulinemia. Pirtobrutinib was developed to reversibly bind BTK, deliver consistently high target coverage regardless of BTK turnover rate, and preserve activity in the presence of the C481 acquired resistance mutations. Interested patients and physicians can contact the Loxo@Lilly Physician and Patient BTK Clinical Trial Hotline at 1-855-LOXO-305 or email clinicaltrials@loxooncology.com.

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 pirtobrutinib in patients previously treated for mantle cell lymphoma (MCL), chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), or other non-Hodgkin lymphomas (NHL).

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 1/1b study is safety, and secondary endpoints include pharmacokinetics and preliminary efficacy of the drug combinations. The primary endpoint for Phase 2 is overall response rate. Secondary endpoints include duration of response, overall survival, safety, and pharmacokinetics.

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 47 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, Twitter and LinkedIn. P-LLY

Lilly Forward-Looking Statement
This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about pirtobrutinib for the potential treatment of previously treated chronic lymphocytic leukemia, small lymphocytic lymphoma, mantle cell lymphoma, Richter transformation, and Waldenström macroglobulinemia and the timeline for future readouts, presentations, and other milestones relating to pirtobrutinib and its clinical trials 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 studies will be completed as planned, that future study results will be consistent with the results to date, that pirtobrutinib will prove to be a safe and effective treatment for relevant indications, or that pirtobrutinib will receive regulatory approvals or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent 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.

Refer to:
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