Loxo Oncology at Lilly Announces Details of Presentations at the 2021 American Society of Hematology (ASH) Annual Meeting

November 4, 2021

INDIANAPOLIS, Nov. 4, 2021 /PRNewswire/ -- Loxo Oncology at Lilly, a research and development group of Eli Lilly and Company (NYSE: LLY), today announced that study investigators will present data from the pirtobrutinib development program at the American Society of Hematology (ASH) Annual Meeting to be held December 11-14, 2021 in Atlanta, GA and virtually. Pirtobrutinib is an investigational, highly selective, non-covalent (reversible) Bruton's tyrosine kinase (BTK) inhibitor.

The pirtobrutinib oral presentations will provide updated clinical data from the ongoing Phase 1/2 BRUIN clinical trial in previously treated chronic lymphocytic leukemia, small lymphocytic lymphoma, and mantle cell lymphoma. The submitted abstracts utilized a September 2020 data cut-off date, and the presentations will utilize a July 2021 data cut-off date.

Additionally, two real-world evidence database studies will be shared: the first on outcomes for patients with chronic lymphocytic leukemia previously treated with a covalent BTK inhibitor and a BCL2 inhibitor will be presented in a poster presentation and the second on outcomes for patients with mantle cell lymphoma following covalent BTK inhibitor therapy will be published as an online-only abstract.

The schedule for the oral and poster presentations are as follows:

Presentation title: Pirtobrutinib, A Highly Selective, Non-Covalent BTK Inhibitor in Previously Treated CLL/SLL: Updated Results from the Phase 1/2 BRUIN Study
Publication Number: 391
Session: 642. Chronic Lymphocytic Leukemia: Clinical and Epidemiological I
Session Date and Time: Sunday, December 12, 2021, 9:30 a.m.- 11:00 a.m. ET
Presentation Time: 9:30 AM
Location: Georgia World Congress Center, B401-B402 and online
Presenter: Anthony R. Mato, M.D.

Presentation Title: Pirtobrutinib, A Highly Selective, Non-Covalent BTK Inhibitor in Previously Treated Mantle Cell Lymphoma: Updated Results from the Phase 1/2 BRUIN Study
Publication Number: 381
Session: 623. Mantle Cell, Follicular, and Other B-Cell Lymphomas: Clinical and Epidemiological: Front-line Induction Therapy and Novel Agents After Relapse
Session Date and Time: Sunday, December 12, 2021, 9:30 a.m. - 11:00 a.m. ET
Presentation Time: 10:00 AM
Location: Georgia World Congress Center, Thomas Murphy Ballroom 1-2
Presenter: Michael L. Wang, M.D.

Presentation Title: Outcomes for Patients with Chronic Lymphocytic Leukemia Previously Treated with a Covalent BTK Inhibitor and BCL2 Inhibitor in the United States: A Real-World Database Study
Publication Number: 3743
Session: 642. Chronic Lymphocytic Leukemia: Clinical and Epidemiological: Poster III
Session Date: Monday, December 13, 2021
Presentation Time: 6:00 p.m. - 8:00 p.m. ET
Location: Georgia World Congress Center, Hall B5
Presenter: Anthony R. Mato, M.D.

About Pirtobrutinib (LOXO-305)
Pirtobrutinib is an investigational, highly selective, non-covalent (reversible) 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, mantle cell lymphoma, Waldenström macroglobulinemia, and marginal zone lymphoma. Currently available covalent BTK inhibitors irreversibly inhibit BTK and the long-term efficacy of these therapies can be limited by acquired resistance, most commonly through BTK C481 mutations. In rapidly growing tumors with inherently high rates of BTK turnover, resistance to covalent BTK therapies may be the result of incomplete target inhibition. Pirtobrutinib was designed to reversibly bind BTK, deliver consistently high target coverage regardless of BTK turnover rate, preserve activity in the presence of the C481 acquired resistance mutations, and avoid off-target kinases that have complicated the development of both covalent and investigational non-covalent BTK inhibitors. Interested patients and physicians can contact the Loxo Oncology at 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
This first-in-human, global, multi-center Phase 1/2 trial evaluates pirtobrutinib as a single agent in patients with previously treated chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), or non-Hodgkin's lymphomas (NHL). The trial includes a Phase 1 dose escalation phase and a Phase 2 dose expansion phase. The Phase 1 dose escalation enrolls patients with CLL/SLL or NHL who have received at least two prior lines of therapy and have progressed or are intolerant to standard of care. The dose escalation phase followed a "3+3" design with pirtobrutinib dosed orally in 28-day cycles. As dose cohorts were cleared, additional patients could enroll in cleared cohorts and intra-patient dose escalation was permitted. The

primary objective of the Phase 1 portion of the trial is to determine the maximum tolerated dose and recommended Phase 2 dose. Key secondary objectives include measures of safety, pharmacokinetics, and anti-tumor activity (i.e. Overall Response Rate (ORR) and Duration of Response, as determined by appropriate histology-specific response criteria). In the Phase 2 dose expansion, patients are enrolled across various cohorts, depending on disease type and prior therapy. The primary endpoint for Phase 2 is ORR. Secondary endpoints include duration of response (DOR), overall survival (OS), safety, and pharmacokinetics (PK).

About Loxo Oncology at Lilly
Loxo Oncology at Lilly was created in December 2019, combining the Lilly Research Laboratories oncology organization and Loxo Oncology, which was acquired by Lilly in early 2019. Loxo Oncology at Lilly brings together the focus and spirit of a biotech with the scale and resources of large pharma, with the goal of rapidly delivering impactful new medicines for people with cancer. Our approach centers on creating new oncology medicines that unequivocally work early in clinical development and will matter to patients.

About Eli Lilly and Company
Lilly is a global health care leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at lilly.com and lilly.com/newsroom. 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 Lilly's pirtobrutinib for the potential treatment of previously treated chronic lymphocytic leukemia, small lymphocytic lymphoma and mantle cell lymphoma and the timeline for future readouts, presentations, and other milestones relating to pirtobrutinib 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 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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