Loxo Oncology at Lilly Announces Details of LOXO-305 Presentations at the 2020 American Society of Hematology (ASH) Annual Meeting

November 5, 2020

INDIANAPOLIS, Nov. 5, 2020 /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 LOXO-305 development program at the American Society of Hematology (ASH) Annual Meeting to be held December 5-8, 2020. LOXO-305 is an investigational, highly selective, non-covalent Bruton's tyrosine kinase (BTK) inhibitor.

The LOXO-305 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, mantle cell lymphoma, Waldenström's macroglobulinemia, and other non-Hodgkin lymphomas. The submitted abstracts utilized an April 2020 data cut-off date, and the presentations will utilize a September 2020 data cut-off date.

Additionally, a pre-clinical analysis of LOXO-305 alone and in combination with venetoclax, rituximab, R-CHOP or obinutuzumab will be presented in a poster presentation.

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

Presentation Title: LOXO-305, A Next Generation, Highly Selective, Non-Covalent BTK Inhibitor in Previously Treated Mantle Cell Lymphoma, Waldenström's Macroglobulinemia, and Other Non-Hodgkin Lymphomas: Results from the Phase 1/2 BRUIN Study
Abstract Number: 117
Presentation Date & Time: Saturday, December 5, 2020, 9:30 a.m. PT
Session: 623. Mantle Cell, Follicular, and Other Indolent B-Cell Lymphoma—Clinical Studies: Mantle Cell Lymphoma Clinical Trials
Presenter: Michael L. Wang. M.D.

Presentation Title: LOXO-305, A Next Generation, Highly Selective, Non-Covalent BTK Inhibitor in Previously Treated CLL/SLL: Results from the Phase 1/2 BRUIN Study
Abstract Number: 542
Presentation Date & Time: Monday, December 7, 2020, 7:00 a.m. PT
Session Name: 642. CLL: Therapy, excluding Transplantation
Presenter: Anthony R. Mato, M.D.

Poster Title: *In Vivo* Pre-Clinical Evaluation of LOXO-305 Alone and in Combination with Venetoclax, Rituximab, R-CHOP or Obinutuzumab on Human Xenograft Lymphoma Tumor Models in Mice
Abstract Number: 1179
Presentation Date: Saturday, December 5, 2020
Session Name: 625. Lymphoma: Pre-Clinical—Chemotherapy and Biologic Agents: Poster I

About LOXO-305
LOXO-305 is an investigational, oral, highly selective, 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, mantle cell lymphoma, Waldenström macroglobulinemia, and marginal zone lymphoma. Currently available 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. LOXO-305 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 Trial
This first-in-human, global, multi-center Phase 1/2 trial evaluates LOXO-305 as a single agent in patients with previously treated chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), or non-Hodgkin's lymphomas (NHL). The primary objective of the Phase 1 portion of the trial is to determine the maximum tolerated dose or recommended Phase 2 dose. Key secondary objectives include measures of safety, pharmacokinetics, and anti-tumor activity (i.e. Overall Response Rate and Duration of Response, as determined by appropriate histology-specific response criteria). 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. In the Phase 2 dose expansion phase, patients are enrolled across various cohorts, depending on disease type and prior therapy.

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 LOXO-305 for the potential treatment of previously treated chronic lymphocytic leukemia, small lymphocytic lymphoma and non-Hodgkin lymphoma and reflects Lilly's current belief. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that studies will complete as planned, that future study results will be consistent with the results to date, or that LOXO-305 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.

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