Eli Lilly and Company to Present Multiple Abstracts for LOXO-305 at ASH 2019

November 6, 2019

INDIANAPOLIS, Nov. 6, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that multiple abstracts from its LOXO-305 program have been accepted for presentation at the 61st American Society of Hematology Annual Meeting and Exposition to be held December 7-10, 2019 in Orlando, Florida. LOXO-305 is a next-generation, highly selective, non-covalent BTK inhibitor.

There will be two LOXO-305 oral presentations. The first will provide an analysis of interim Phase 1 clinical trial data from the ongoing first-in-human, Phase 1/2 Trial of LOXO-305 in patients with pretreated B-cell malignancies. The second oral presentation will provide a preclinical analysis of LOXO-305's activity in ibrutinib-resistant CLL, based on patient-derived samples. Finally, a poster presentation will provide a preclinical analysis of LOXO-305's activity against diverse BTK C481 substitution mutations.

The presentation details, including dates and times, are highlighted below:

LOXO-305 Oral Presentation Session Date & Time: Sunday, December 8, 2019, 4:30-6:00 pm ET
Title: Results from a First-in-Human, Proof-of-Concept Phase 1 Trial in Pretreated B-Cell Malignancies for Loxo-305, a Next-Generation, Highly Selective, Non-Covalent BTK Inhibitor
Abstract Number: 501
Session Title: CLL: Therapy, excluding Transplantation: BTK Inhibitors and CAR T Cells in CLL
Presenter: Anthony Mato

LOXO-305 Oral Presentation Session Date & Time: Sunday, December 8, 2019, 12:00-1:30 pm ET
Title: LOXO-305: Targeting C481S Bruton Tyrosine Kinase in Patients with Ibrutinib-Resistant CLL
Abstract Number: 478
Session Title: CLL: Biology and Pathophysiology, excluding Therapy: Mechanisms of Response and Resistance to Targeted Agents
Presenter: Aishath Naeem

LOXO-305 Poster Presentation Session Date & Time: Monday, December 9, 2019, 6:00-8:00 pm ET
Title: Loxo-305, a Highly Selective and Non-Covalent Next Generation BTK Inhibitor, Inhibits Diverse BTK C481 Substitution Mutations
Abstract Number: 4644
Session Title: Chemical Biology and Experimental Therapeutics: Poster III
Presenter: Eliana Gomez

About LOXO-305
LOXO-305 is an investigational, novel, 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, Waldenstrom's macroglobulinemia, mantle cell lymphoma and marginal zone lymphoma. Currently available BTK inhibitors irreversibly inhibit BTK and the long-term efficacy of these therapies has been limited by acquired resistance, most commonly through BTK C481 mutations, and intolerance, due to off target inhibition of other cellular targets. LOXO-305 was designed to reversibly bind BTK, 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 Physician and Patient BTK Clinical Trial Hotline at 1-855-LOXO-305 or email clinicaltrials@loxooncology.com.

About the LOXO-305 Phase 1/2 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, six cohorts are planned to allow for the characterization of the preliminary anti-tumor activity of LOXO-305: 1) CLL/SLL failed prior BTK inhibitor with BTK C481 mutation; 2) CLL/SLL failed prior BTK inhibitor without BTK C481 mutation; 3) Waldenstrom's macroglobulinemia (WM), mantle cell lymphoma (MCL) or marginal zone lymphoma (MZL) failed prior BTK inhibitor with BTK C481 mutation; 4) WM, MCL or MZL failed prior BTK inhibitor without BTK C481 mutation; 5) CLL/SLL, WM, MCL or MZL intolerant to prior BTK inhibitor; 6) CLL/SLL, WM, MCL or MZL failed prior BTK inhibitor with unknown BTK C481 mutation status and other CLL/SLL, WM, CML, MZL or other NHL patients not meeting the definitions of Cohorts 1 through 5.

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 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.

Refer to:Nicole Hebert, hebert_nicole@lilly.com, (317) 701-9984 – media
Kevin Hern; hern_kevin_r@lilly.com; (317) 277-1838 – investors

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