Loxo Oncology at Lilly Announces Details of Presentations at 2021 AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics

October 7, 2021

INDIANAPOLIS, Oct. 7, 2021 /PRNewswire/ -- Loxo Oncology at Lilly, a research and development group of Eli Lilly and Company (NYSE: LLY), today announced that preclinical characterization data for two new agents, LOXO-783 and LOXO-435, will be presented at the 2021 AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics, held October 7-10, 2021. The data will be presented as part of the plenary session titled “New Drugs on the Horizon II” as well as in individual poster presentations.

LOXO-783 is a potent, highly mutant-selective and brain-penetrant allosteric PI3Kα H1047R inhibitor that is designed to spare wild-type PI3Kα, other PI3K isofoms, and other kinases. LOXO-435 is a potent and highly isoform-selective FGFR3 inhibitor with preserved activity against FGFR3 gatekeeper resistance mutations. Investigational new drug applications (INDs) are planned for both programs in 2022.

“LOXO-783 and LOXO-435 each represent years of diligent work by our discovery teams to build molecules that meet exacting target product profiles. In the case of both PI3Kα H1047R-mutated cancers and FGFR3-mutated cancers, patients deserve medicines purpose-built to their disease biology and we believe that these molecules have the potential to markedly improve on the efficacy and tolerability of existing agents,” said Jacob Van Naarden, chief executive officer of Loxo Oncology at Lilly and President of Lilly Oncology. “We look forward to filing INDs for both programs in 2022 and subsequently moving into the clinic.”

Details on oral and poster presentations are below:

**Presentation Title:** Discovery of mutant-selective PI3Kα and isoform-selective FGFR3 inhibitors: Insights from the Loxo Oncology at Lilly Discovery Model

**Presentation Date & Time:** Saturday, October 9, 4:00 p.m. ET

**Session:** Plenary Session 6: New Drugs on the Horizon II

**Presenter:** David Hyman, M.D.

**Poster Title:** Preclinical characterization of LOXO-435 (LOX-24350), a potent and highly isoform-selective FGFR3 inhibitor

**Abstract Number:** 141

**Available:** Thursday, October 7, 9 a.m. ET

**Presenter:** Joshua Ballard

**Poster Title:** Preclinical characterization of LOXO-783 (LOX-22783), a highly potent, mutant-selective and brain-penetrant allosteric PI3Kα H1047R inhibitor

**Abstract Number:** 142

**Available:** Thursday, October 7, 9 a.m. ET

**Presenter:** Anke Klippel, Ph.D.

**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.

**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 therapies under development by Lilly and Loxo Oncology at Lilly, presentation of related data, and Lilly and Loxo Oncology's strategy and pipeline, 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 can be no guarantee that studies will be initiated or completed as planned, that future study results will be consistent with the results to date, or that any of these therapies will receive initial regulatory approvals or approvals for additional indications, as applicable, 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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