



Data Presentations at ASCO 2019 Highlight Lilly's Targeted Approach to Developing Treatments for Patients Living with Cancer

May 15, 2019

**Lung cancer highlights to include the first presentation of RELAY results and additional findings from KEYNOTE-189
Lilly to share data from Phase 3 ANNOUNCE trial in people with advanced soft tissue sarcoma**

INDIANAPOLIS, May 15, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that data from a number of studies across the company's oncology product portfolio will be presented at the 55th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, May 31-June 4, 2019. Data from 23 oral presentations and posters underscore Lilly Oncology's focus on making a meaningful difference in the lives of people living with cancer, especially those with hard-to-treat tumor types.

"Lilly data at this year's ASCO demonstrate our commitment to offering treatment solutions for patients with the greatest need. We look forward to sharing these findings, with the hope that they will shed light on our progress and future opportunities in difficult-to-treat cancers," said Maura Dickler, M.D., vice president, late phase development, Lilly Oncology. "We are excited to present the first results from RELAY, a Phase 3 study of ramucirumab in metastatic EGFR-mutated non-small cell lung cancer. Lilly will also share early-phase data from several investigational molecules as well as results from collaborative studies. This includes updated findings from the Phase 3 KEYNOTE-189 study of the pemetrexed-pembrolizumab-platinum chemotherapy combination, which has been established as the standard of care for the treatment of first-line metastatic nonsquamous non-small cell lung cancer."

Lung Cancer Data at ASCO

Lilly has a decades-old heritage in developing practice-changing medicines for the treatment of lung cancer. Lilly has developed multiple thoracic oncology treatments and continues to study marketed products and investigational molecules in new combinations and settings where they could help specific patient populations.

RELAY is a global, randomized, double-blind Phase 3 trial evaluating ramucirumab in combination with erlotinib, compared to placebo in combination with erlotinib, as a first-line treatment in patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have activating EGFR mutations.

The KEYNOTE-189 trial, a randomized, double-blind, placebo-controlled Phase 3 study, evaluated pemetrexed in combination with pembrolizumab and cisplatin or carboplatin compared with pemetrexed in combination with placebo and cisplatin or carboplatin, in untreated patients with metastatic nonsquamous NSCLC, regardless of PD-L1 expression. The KEYNOTE-189 study was conducted by Merck (known as MSD outside the U.S. and Canada) in collaboration with Lilly.

Dr. Dickler added, "In addition to our lung cancer data at ASCO this year, we will present results of the Phase 3 ANNOUNCE trial, which studied olaratumab in combination with doxorubicin in soft tissue sarcoma. Unfortunately, this study did not confirm a survival benefit seen in a prior Phase 2 trial. We believe it's important to share these results to inform the scientific community and to apply these learnings to the future investigation of new therapies in this heterogeneous and difficult-to-treat cancer."

Select studies, along with the dates, times and locations of their data sessions, are highlighted below.

Ramucirumab

Abstract #9000: RELAY: A multinational, double-blind, randomized Phase 3 study of erlotinib (ERL) in combination with ramucirumab (RAM) or placebo (PL) in previously untreated patients with epidermal growth factor receptor mutation-positive (EGFRm) metastatic non-small cell lung cancer (NSCLC) (Kazuhiko Nakagawa)

- Oral Abstract Session; Lung Cancer—Non-Small Cell Metastatic
- Monday, June 3; 8:00 – 8:12 a.m. CDT; Hall B1

Abstract #2528: Ramucirumab (Ram) and durvalumab (Durva) treatment of metastatic non-small cell lung cancer (NSCLC), gastric/gastroesophageal junction (G/GEJ) adenocarcinoma, and hepatocellular carcinoma (HCC) following progression on systemic treatment(s) (Yung-Jue Bang)

- Poster Session: Poster Board #172; Developmental Immunotherapy and Tumor Immunobiology
- Saturday, June 1; 8:00 – 11:00 a.m. CDT; Hall A

Abstract #4073: Ramucirumab (RAM) for sorafenib intolerant patients with hepatocellular carcinoma (HCC) and elevated baseline alpha fetoprotein (AFP): Outcomes from two randomized phase 3 studies (REACH, REACH2) (Josep M Llovet)

- Poster Session: Poster Board #178; Gastrointestinal (Noncolorectal) Cancer

- Monday, June 3; 8:00 – 11:00 a.m. CDT; Hall A

Pemetrexed

Abstract #9013: KEYNOTE-189: Updated OS and progression after the next line of therapy (PFS2) with pembrolizumab (pembro) plus chemo with pemetrexed and platinum vs placebo plus chemo for metastatic nonsquamous NSCLC (Shirish M. Gadgeel)

- Poster Session, Poster Board #336, Lung Cancer—Non-Small Cell Metastatic
- Sunday, June 2; 8:00 – 11:00 a.m. CDT; Hall A
- Poster Discussion Session on Sunday, June 2; 4:30 – 6:00 p.m. CDT; Hall D1

Olaratumab

Abstract #LBA3: ANNOUNCE: A randomized, placebo (PBO)-controlled, double-blind, phase (Ph) III trial of doxorubicin (dox) + olaratumab versus dox + PBO in patients (pts) with advanced soft tissue sarcomas (STS) (William D. Tap)

- Plenary Session
- Sunday, June 2; 2:45 – 3:00 p.m. CDT; Hall B1

Abemaciclib

Abstract #1017: A phase II study of abemaciclib in patients (pts) with brain metastases (BM) secondary to HR+, HER2- metastatic breast cancer (MBC) (Carey K. Anders)

- Poster Session; Poster Board #98; Breast Cancer—Metastatic
- Sunday, June 2; 8:00 – 11:00 a.m. CDT; Hall A
- Poster Discussion Session on Sunday, June 2; 11:15 a.m. – 12:45 p.m. CDT; Hall D2

Abstract #1042: Next-generation sequencing (NGS) results among hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) metastatic breast cancer (MBC) patients treated with a CDK4 & 6 inhibitor: A retrospective observational study based on real-world data (Erika Paige Hamilton)

- Poster Session: Poster Board #123; Breast Cancer—Metastatic
- Sunday, June 2; 8:00 – 11:00 a.m. CDT; Hall A

LOXO-292

Abstract # TPS10066: A phase I study of LOXO-292, a highly selective RET inhibitor, in pediatric patients with RET-altered cancers (Steven G. DuBois)

- Poster Session: Poster Board #447b; Pediatric Oncology
- Saturday, June 1; 8:00 – 11:00 a.m. CDT; Hall A

Abstract #10045: First experience of LOXO-292 in the management of pediatric patients with RET-altered cancers (Ulrike Gerdemann)

- Poster Session: Poster Board #427; Pediatric Oncology
- Saturday, June 1; 8:00 – 11:00 a.m. CDT; Hall A

CSF-1R

Abstract #2548: Phase 1 study of LY3022855, a colony-stimulating factor-1 receptor (CSF-1R) inhibitor, in patients with metastatic breast cancer (MBC) or metastatic castration-resistant prostate cancer (MCRPC) (Karen A. Autio)

- Poster Session: Poster Board #192; Developmental Immunotherapy and Tumor Immunobiology
- Saturday, June 1; 8:00 – 11:00 a.m. CDT; Hall A

ERK Inhibitor

Abstract #3001: A phase I dose escalation (DE) study of ERK inhibitor, LY3214996, in advanced (adv) cancer (CA) patients (pts) (Shubham Pant)

- Oral Abstract Session; Developmental Therapeutics and Tumor Biology (Nonimmuno)
- Monday, June 3; 8:12 – 8:24 a.m. CDT; S406

PI3 KINASE/mTOR

Abstract #5009: Phase 1b/2 study of enzalutamide (ENZ) with LY3023414 (LY) or placebo (PL) in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) after progression on abiraterone (Christopher Sweeney)

- Poster Session: Poster Board #121; Genitourinary (Prostate) Cancer
- Saturday, June 1; 1:15 – 4:15 p.m. CDT; Hall A

- Poster Discussion Session on Saturday, June 1; 4:30 – 6:00 p.m. CDT; Arie Crown Theater

Prexasertib

Abstract #3091: A phase Ib study of prexasertib, a checkpoint kinase (CHK1) inhibitor, and LY3023414, a dual inhibitor of class I phosphatidylinositol 3-kinase (PI3K) and the mammalian target of rapamycin (mTOR) in patients with advanced solid tumors (David S. Hong)

- Poster Session: Poster Board #83; Developmental Therapeutics and Tumor Biology (Nonimmuno)
- Saturday, June 1; 8:00 – 11:00 a.m. CDT; Hall A

Ralimetinib

Abstract #5537: A randomized, double-blind, placebo-controlled phase Ib/II study of ralimetinib, a p38 MAPK inhibitor, plus gemcitabine (G) and carboplatin (C) versus GC for women with recurrent platinum-sensitive ovarian cancer (Ignace Vergote)

- Poster Session: Poster Board #360; Gynecologic Cancer
- Saturday, June 1; 1:15 – 4:15 p.m. CDT; Hall A

TIM-3/PD-L1

Abstract #TPS2654: A phase Ia/b study of TIM-3/PD-L1 bispecific antibody in patients with advanced solid tumors (Matthew David Hellmann)

- Poster Session: Poster Board #293a; Developmental Immunotherapy and Tumor Immunobiology
- Saturday, June 1; 8:00 – 11:00 a.m. CDT; Hall A

Galunisertib

Abstract #4124: A phase Ib dose-escalation and cohort-expansion study of safety and activity of the transforming growth factor (TGF) β receptor I kinase inhibitor galunisertib plus the anti-PD-L1 antibody durvalumab in metastatic pancreatic cancer (Davide Melisi)

- Poster Session: Poster Board #229; Gastrointestinal (Noncolorectal) Cancer
- Monday, June 3; 8:00 – 11:00 a.m. CDT; Hall A

Global Patient Outcomes & Real World Evidence

Abstract #2035: Clinical characteristics, treatment (Tx) patterns, and overall survival (OS) in advanced (Adv) NSCLC patients (Pts) with and without brain metastases (BM) (Emily Nash Smyth)

- Poster Session: Poster Board #224; Central Nervous System Tumors
- Sunday, June 2; 8:00 – 11:00 a.m. CDT; Hall A

Abstract #2014: Genomic characterization of lung tumors and metastatic (Met) sites in advanced (Adv) NSCLC (Melinda D. Willard)

- Poster Session: Poster Board #203; Central Nervous System Tumors
- Sunday, June 2; 8:00 – 11:00 a.m. CDT; Hall A
- Poster Discussion Session on Sunday, June 2; 4:30 - 6:00 p.m.; S404

Sintilimab

Abstract #7504: Sintilimab for relapsed/refractory (r/r) extranodal NK/T cell lymphoma (ENKTL): A multicenter, single-arm, phase 2 trial (ORIENT-4) (Rong Tao)

- Oral Abstract Session; Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia
- Tuesday, June 4; 10:57 – 11:09 a.m. CDT; E451

Abstract #4042: Efficacy and safety of sintilimab in combination with XELOX in first-line gastric or gastroesophageal junction carcinoma (GC/GEJC) (Nong Xu)

- Poster Session: Poster Board #147; Gastrointestinal (Noncolorectal) Cancer
- Monday, June 3; 8:00 – 11:00 a.m. CDT; Hall A

Abstract #7533: Sintilimab for relapsed/refractory classical Hodgkin's lymphoma: Extended follow-up on the multicenter, single-arm phase II ORIENT-1 study (Hang Su)

- Poster Session: Poster Board #287; Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia
- Monday, June 3; 8:00 – 11:00 a.m. CDT; Hall A

Abstract #8531: Efficacy and safety of neoadjuvant PD-1 blockade with sintilimab in resectable squamous non-small cell lung cancer (sqNSCLC) (Ning Li)

- Poster Session: Poster Board #287; Lung Cancer—Non-Small Cell Local-Regional/Small Cell/Other Thoracic Cancers
- Sunday, June 2; 8:00 – 11:00 a.m. CDT; Hall A

Abstract #7534: Circulating tumor DNA to predict response and resistance by anti-PD-1 therapy in Chinese relapsed/refractory classic Hodgkin lymphoma (Hang Su)

- Poster Session: Poster Board #288; Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia
- Monday, June 3; 8:00 – 11:00 a.m. CDT; Hall A

About Lilly Oncology

For more than 50 years, Lilly has been dedicated to delivering life-changing medicines and support to people living with cancer and those who care for them. Lilly is determined to build on this heritage and continue making life better for all those affected by cancer around the world. To learn more about Lilly's commitment to people with cancer, please visit www.LillyOncology.com.

About Eli Lilly and Company

Lilly is a global healthcare 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 www.lilly.com and newsroom.lilly.com/social-channels. P-LLY

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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 oncology portfolio and pipeline, including ramucirumab, pemetrexed, olaratumab, abemaciclib, LOXO-292, CSF-1R, ERK inhibitor, PI3 KINASE/mTOR, prexasertib, ralimetinib, TIM-3/PD-L1, galunisertib and sintilimab. This press release reflects Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other risks, there can be no guarantee that these treatment options will receive regulatory approval, or, if approved, that it will achieve intended benefits or become a commercially successful product. 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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