



Lilly Data at ASCO Illustrate Patient-Driven Advances in Cancer Care

May 16, 2018

First presentation of findings from the ramucirumab REACH-2 study - the first positive Phase 3 hepatocellular carcinoma trial in a biomarker-selected population

Research across the MONARCH clinical development program reinforcing the benefit of abemaciclib in advanced breast cancer will also be presented

INDIANAPOLIS, May 16, 2018 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that new results from a number of studies across the company's oncology product and pipeline portfolio will be presented at the 54th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, June 1-5, 2018. Data from 30 oral presentations, poster presentations and e-publications underscore Lilly Oncology's focus on making a meaningful difference in the lives of people living with cancer through clinical development and collaboration.

Highlights include the late-breaking oral presentation of the Phase 3 REACH-2 trial results for ramucirumab as a single agent in the second-line treatment of people with hepatocellular carcinoma (HCC), also known as liver cancer. Key abemaciclib data include findings from the MONARCH 2 study evaluating abemaciclib plus fulvestrant in pre- and peri-menopausal women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced breast cancer, as well as data from the MONARCH 2 and 3 studies investigating the impact of the addition of abemaciclib to fulvestrant or a nonsteroidal aromatase inhibitor (NSAI) on the start of subsequent chemotherapy. Additionally, data will be presented from Lilly's ongoing immuno-oncology clinical collaborations with Merck (known as MSD outside the U.S. and Canada). These include additional results from the KEYNOTE-021 (Cohort G) and KEYNOTE-189 trials evaluating pemetrexed plus platinum chemotherapy in combination with pembrolizumab in the first-line treatment of metastatic nonsquamous non-small cell lung cancer (NSCLC), as well as results from the study of ramucirumab and pembrolizumab in multiple tumor types and the study of abemaciclib and pembrolizumab in HR+, HER- metastatic breast cancer.

"The data presented at ASCO demonstrate Lilly's steadfast commitment to advancing medicines in areas where patients experience the greatest need," said Levi Garraway, M.D., Ph.D., senior vice president, global development and medical affairs, Lilly Oncology. "We look forward to the first presentation of the REACH-2 trial results. Advanced liver cancer is an aggressive disease, and ramucirumab has now demonstrated a survival benefit in a group of patients associated with particularly poor prognosis in two randomized clinical studies. We are also sharing several other study findings aimed to leverage our understanding of biomarkers and new therapeutic applications to benefit patients with hard-to-treat cancers."

Ramucirumab REACH-2 Data at ASCO

REACH-2 is the first positive Phase 3 HCC trial in a biomarker-selected patient population, and confirms the results of the first REACH study in patients who had a high alpha-fetoprotein (AFP-High). The REACH-2 study evaluated the benefit of ramucirumab treatment in HCC patients who were intolerant to, or had disease progression while on or following treatment with, sorafenib and AFP-High, defined as an AFP of ≥ 400 ng/mL. Approximately half of all advanced HCC patients are AFP-High and these patients are among those with the poorest prognosis relative to the general HCC patient population. While there have been some recent advances in treating HCC, there remains a very high unmet need for patients in this treatment setting.

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

Ramucirumab

Abstract #4003: REACH-2: A randomized, double-blind, placebo-controlled Phase 3 study of ramucirumab versus placebo as second-line treatment in patients with advanced hepatocellular carcinoma (HCC) and elevated baseline alpha-fetoprotein (AFP) following first-line sorafenib. (Andrew X. Zhu)

- Oral Abstract Session; Gastrointestinal (Noncolorectal) Cancer
- Monday, June 4; 4:00 – 4:12 p.m. CDT; Arie Crown Theater

Abstract #4036: Randomized, double-blind, Phase 2 study of S-1 plus oxaliplatin (SOX) with or without ramucirumab (RAM) as first-line therapy followed by paclitaxel plus RAM as second-line therapy in patients with advanced gastric or gastroesophageal junction adenocarcinoma (AGC). (Kei Muro)

- Poster Session: Poster Board #225; Gastrointestinal (Noncolorectal) Cancer
- Sunday, June 3; 8:00 – 11:30 a.m. CDT; Hall A

Abstract #4044: Effect of post-discontinuation therapy (PDT) on survival in metastatic gastric-gastroesophageal junction (G-GEJ) adenocarcinoma patients from the RAINFALL trial: an exploratory analysis. (Kohei Shitara)

- Poster Session: Poster Board #233; Gastrointestinal (Noncolorectal) Cancer
- Sunday, June 3; 8:00 – 11:30 a.m. CDT; Hall A

Abstract #4526: Ramucirumab (RAM) exposure-response (ER) relationship in RANGE, a randomized Phase 3 trial of docetaxel (DOC) with or without RAM in advanced urothelial carcinoma (UC) patients (pts) who progressed on or after platinum therapy. (Ronald De Wit)

- Poster Session: Poster Board #352; Genitourinary (Nonprostate) Cancer
- Saturday, June 2; 8:00 – 11:30 a.m. CDT; Hall A

Abstract #4542: A subgroup analysis of the East Asia population in RANGE: a randomized Phase 3 study of docetaxel (DOC) with or without ramucirumab (RAM) in platinum-refractory advanced or metastatic urothelial carcinoma (UC). (Nobuaki Matsubara)

- Poster Session: Poster Board #368; Genitourinary (Nonprostate) Cancer
- Saturday, June 2; 8:00 – 11:30 a.m. CDT; Hall A

Abstract #9053: Efficacy and safety results of ramucirumab in combination with osimertinib in advanced T790M-positive EGFR-mutant NSCLC. (David Planchard)

- Poster Session: Poster Board #376; Lung Cancer—Non-Small Cell Metastatic
- Sunday, June 3; 8:00 – 11:30 a.m. CDT; Hall A

Abemaciclib

Abstract #1002: Abemaciclib for pre/perimenopausal women with HR+, HER2- advanced breast cancer. (Patrick Neven)

- Oral Abstract Session: Breast Cancer—Metastatic
- Sunday, June 3; 8:00 – 11:00 a.m. CDT; Presentation Time 8:24 – 8:36 a.m. CDT; Hall D2

Abstract #1048: Impact of abemaciclib on the time to subsequent chemotherapy and the time to second disease progression across the MONARCH 2 and 3 studies. (Sara M. Tolaney)

- Poster Session: Poster Board #129; Breast Cancer—Metastatic
- Saturday, June 2; 8:00 – 11:30 a.m. CDT; Hall A

Abstract #1049: Health-related quality of life (HRQoL) in MONARCH 2: Abemaciclib plus fulvestrant in women with HR+, HER2- advanced breast cancer (ABC) who progressed on endocrine therapy. (Peter A. Kaufman)

- Poster Session: Poster Board #130; Breast Cancer—Metastatic
- Saturday, June 2; 8:00 – 11:30 a.m. CDT; Hall A

Abstract #1053: The association of early toxicity and outcomes for patients treated with abemaciclib. (Hope S. Rugo)

- Poster Session: Poster Board #134; Breast Cancer—Metastatic
- Saturday, June 2; 8:00 – 11:30 a.m. CDT; Hall A

Olaratumab

Abstract #10541: Phase 1 study of olaratumab as monotherapy and in combination with doxorubicin, vincristine/irinotecan, or high-dose ifosfamide in pediatric patients with relapsed or refractory solid tumors: Part A results. (Steven G. DuBois)

- Poster Session: Poster Board #214; Pediatric Oncology
- Saturday, June 2; 8:00 – 11:30 a.m. CDT; Hall A

Abstract #11542: Phase 1b/2 study of olaratumab plus gemcitabine and docetaxel for the treatment of advanced soft tissue sarcoma (STS) (ANNOUNCE 2): Phase 1b results. (Victor Manuel Villalobos)

- Poster Session: Poster Board #287; Sarcoma
- Saturday, June 2; 8:00 – 11:30 a.m. CDT; Hall A

Abstract #11548: Characteristics and clinical outcomes of French patients diagnosed with advanced soft tissue sarcoma (aSTS) in real-life setting: Data from the European sarcoma biological and clinical data banking (ESBCB). (Jean-Yves Blay)

- Poster Session: Poster Board #293; Sarcoma
- Saturday, June 2; 8:00 – 11:30 a.m. CDT; Hall A

Prexasertib

Abstract #2579: A Phase 1b dose-escalation study of prexasertib, a checkpoint kinase 1 (CHK1) inhibitor, in combination with cisplatin in patients with advanced cancer. (Manish R. Patel)

- Poster Session: Poster Board #405; Developmental Therapeutics—Clinical Pharmacology and Experimental Therapeutics
- Monday, June 4; 8:00 – 11:30 a.m. CDT; Hall A

Data from Immuno-Oncology Collaborations

Abstract #9021: Health-related quality of life (HRQoL) in the KEYNOTE-189 study of pembrolizumab (pembro) or placebo (pbo) + pemetrexed (pem) + platinum (plt) for metastatic NSCLC. (Marina Chiara Garassino)

- Poster Discussion Session: Poster Board #344; Lung Cancer—Non-Small Cell Metastatic
- Sunday, June 3; 8:00 – 11:30 a.m. CDT; Hall A
- Poster Discussion Session on Sunday, June 3; 11:30 a.m. – 12:45 p.m. CDT, at Arie Crown Theater

Abstract #9026: 24-month overall survival from KEYNOTE-021 cohort G: Pemetrexed-carboplatin plus pembrolizumab as first-line therapy for advanced nonsquamous NSCLC. (Ryan D. Gentzler)

- Poster Session: Poster Board #349; Lung Cancer—Non-Small Cell Metastatic
- Sunday, June 3; 8:00 – 11:30 a.m. CDT; Hall A

Abstract #3059: Activity of ramucirumab (R) with pembrolizumab (P) by PD-L1 expression in advanced solid tumors: Phase 1a/b study in later lines of therapy. (Roy S. Herbst)

- Poster Session: Poster Board #273; Developmental Therapeutics—Immunotherapy
- Monday, June 4; 8:00 – 11:30 a.m. CDT; Hall A

Abstract #1059: Updated efficacy, safety, & PD-L1 status of patients with HR+, HER2- metastatic breast cancer administered abemaciclib plus pembrolizumab. (Sara M. Tolaney)

- Poster Session: Poster Board #140; Breast Cancer—Metastatic
- Saturday, June 2; 8:00 – 11:30 a.m. CDT; Hall A

Data from Other Collaborations

Abstract #3537: Subgroup analysis by prior anti-VEGF or anti-EGFR target therapy in FRESCO, a randomized, double-blind, Phase 3 trial comparing fruquintinib versus placebo plus best supportive care in Chinese patients with metastatic colorectal cancer (mCRC). (Ruihua Xu)

- Poster Session: Poster Board #30; Gastrointestinal (Colorectal) Cancer
- Sunday, June 3; 8:00 – 11:30 a.m. CDT; Hall A

Abstract #3544: Quality-adjusted time without symptoms or toxicity (Q-TWiST) of patients with metastatic colorectal cancer (mCRC) treated with fruquintinib in the randomized Phase 3 FRESCO trial. (Yu-Xian Bai)

- Poster Session: Poster Board #37; Gastrointestinal (Colorectal) Cancer
- Sunday, June 3; 8:00 – 11:30 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 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) regarding Lilly's oncology portfolio and pipeline, including ramucirumab, abemaciclib, olaratumab, prexasertib, pemetrexed and fruquintinib. 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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