



May 17, 2017

## **Lilly to Present Results from Pivotal Breast Cancer Study of Abemaciclib and New Portfolio Data at ASCO 2017**

### **First presentation of Phase 3 MONARCH 2 study of abemaciclib in combination with fulvestrant in patients with HR+, HER2- advanced breast cancer who progressed on endocrine therapy**

INDIANAPOLIS, May 17, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that new research demonstrating advances in the Company's oncology pipeline and product portfolio will be presented at the 53rd Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, June 2-6, 2017. Data underscore a strategic focus on targeting the biology of cancer to find new ways to fight cancer and transform care for patients. Highlights include oral presentation of Phase 3 data for abemaciclib, an investigational cyclin-dependent kinase (CDK)4 & 6 inhibitor for breast cancer, as well as new data from the Company's ongoing immuno-oncology clinical collaborations with Merck (known as MSD outside the U.S. and Canada) in two trials that are evaluating pemetrexed-plus-carboplatin and ramucirumab, respectively, in combination with Merck's pembrolizumab.

"We are pleased to share how we are building foundational therapeutics with the goal of delivering medicines that help people with cancer live longer and healthier lives," said Levi Garraway, M.D., Ph.D., senior vice president, global development and medical affairs, Lilly Oncology. "We are particularly excited about the latest results from the abemaciclib MONARCH clinical development program, in which we have endeavored to raise the bar with a potential next-generation CDK4 & 6 inhibitor that we believe may improve outcomes for patients living with breast cancer."

"With abemaciclib we hoped to develop an oral CDK4 & 6 inhibitor that could be taken without interruption. In preclinical research, continued disruption was shown to stop tumor cells from entering the cell cycle, which prevents tumor cell growth and, ultimately, promotes tumor cell death that may translate into clinical benefit for breast cancer patients," said Alfonso de Dios, senior research fellow, discovery chemistry research & technologies, Lilly.

#### **Abemaciclib Data at ASCO**

Detailed data from the Phase 3 MONARCH 2 study, which evaluated abemaciclib in combination with fulvestrant in women with hormone-receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced breast cancer, will be presented in an oral presentation. The intent-to-treat population of 669 patients in MONARCH 2 had experienced disease progression on or within 12 months of receiving endocrine treatment in the neoadjuvant or adjuvant setting or while receiving first-line endocrine therapy for metastatic disease.

Additionally, abemaciclib has been shown in preclinical and Phase 1 studies to cross the blood-brain barrier, making this an area of interest for further study. This year's meeting will allow Lilly to share preliminary Phase 2 data evaluating a CDK4 & 6 inhibitor in patients with new or progressive brain metastases secondary to advanced breast cancer, lung cancer or melanoma.

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

#### **Abemaciclib**

- | Abstract #1000: Oral Presentation: Breast Cancer—Metastatic: Saturday, June 3, 2017; 1:15-4:15 p.m. CDT
  - | MONARCH 2: Abemaciclib in combination with fulvestrant in patients with HR+/HER2- advanced breast cancer who progressed on endocrine therapy
  - | Author/Speaker: George W. Sledge, M.D., F.A.S.C.O., Stanford University School of Medicine
  - | Location: Hall D1
- | Abstract #1019: Breast Cancer—Metastatic: Sunday, June 4, 2017; 8:00-11:30 a.m. CDT
  - | Abemaciclib for the treatment of brain metastases (BM) secondary to hormone-receptor-positive (HR+), HER2- breast cancer
  - | Author/Speaker: Sara M. Tolaney, M.D., M.P.H., Dana-Farber Cancer Institute
  - | Location: Hall A (Poster Board #11)
  - | Poster Discussion Session: Sunday, June 4, 2017; 4:45-6:00 p.m. CDT, Hall B1
- | Abstract #TPS1109: Breast Cancer—Metastatic: Sunday, June 4, 2017; 8:00-11:30 a.m. CDT

- | A Phase 2 randomized study to compare abemaciclib plus trastuzumab with or without fulvestrant to standard of care chemotherapy plus trastuzumab in hormone-receptor-positive, HER2-positive, advanced breast cancer (monarchHER)
- | Author/Speaker: Sara M. Tolaney, M.D., M.P.H., Dana-Farber Cancer Institute
- | Location: Hall A (Poster Board #99b)
- | Abstract #TPS4150: Gastrointestinal (Noncolorectal) Cancer: Saturday, June 3, 2017; 8:00-11:30 a.m. CDT
  - | A Phase 2 study of abemaciclib as a monotherapy and in combination with other agents in patients with previously treated metastatic pancreatic ductal adenocarcinoma (PDAC)
  - | Author/Speaker: E. Gabriela Chiorean, M.D., Fred Hutchinson Cancer Research Center
  - | Location: Hall A (Poster Board #132b)

## **Fruquintinib**

- | Abstract #3508: Oral Presentation: Gastrointestinal (Colorectal) Cancer: Monday, June 5, 2017; 3:00-6:00 p.m. CDT
  - | A randomized, double-blind, placebo-controlled, multi-centered Phase 3 trial comparing fruquintinib versus placebo plus best supportive care in Chinese patients with metastatic colorectal cancer (FRESCO)
  - | Author/Speaker: Jin Li, M.D., Fudan University Shanghai Cancer Center, Shanghai Medical College
  - | Location: Hall D2

## **Immuno-Oncology Collaborations with pemetrexed-plus-carboplatin or ramucirumab**

- | Abstract #9094: Lung Cancer—Non-Small Cell Metastatic: Saturday, June 3, 2017; 8:00-11:30 a.m. CDT
  - | First-line carboplatin and pemetrexed (CP) with or without pembrolizumab (pembro) for advanced nonsquamous NSCLC: Updated results of KEYNOTE-021 cohort G
  - | Author/Speaker: Vassiliki Papadimitrakopoulou, M.D., The University of Texas MD Anderson Cancer Center
  - | Location: Hall A (Poster Board #420)
- | Abstract #4046: Gastrointestinal (Noncolorectal) Cancer: Saturday, June 3, 2017; 8:00-11:30 a.m. CDT
  - | Ramucirumab (R) plus pembrolizumab (P) in treatment naive and previously treated advanced gastric or gastroesophageal junction (G/GEJ) adenocarcinoma: A multi-disease Phase 1 study
  - | Author/Speaker: Ian Chau, M.D., F.R.C.P., Royal Marsden Hospital
  - | Location: Hall A (Poster Board #38)

## **Olaratumab**

- | Abstract #TPS2599: Developmental Therapeutics—Clinical Pharmacology and Experimental Therapeutics: Monday, June 5, 2017; 8:00-11:30 a.m. CDT
  - | A Phase 1, open-label, dose-escalation study of olaratumab as a single agent and in combination with doxorubicin, vincristine/irinotecan, or high-dose ifosfamide in pediatric patients with relapsed or refractory solid tumors
  - | Author/Speaker: Leo Mascarenhas, M.B.B.S., M.D., M.S., Children's Center for Cancer and Blood Diseases, Children's Hospital Los Angeles, University of Southern California
  - | Location: Hall A (Poster Board #89b)

## **Emibetuzumab**

- | Abstract #9019: Lung Cancer—Non-Small Cell Metastatic: Saturday, June 3, 2017; 8:00-11:30 a.m. CDT
  - | A randomized, controlled, open-label Phase 2 study of erlotinib (E) with or without the MET antibody emibetuzumab (Emi) as first-line treatment for *EGFR*mt non-small cell lung cancer (NSCLC) patients who have disease control after an eight-week lead-in treatment with erlotinib
  - | Author/Speaker: Giorgio V. Scagliotti, M.D., Ph.D., Department of Oncology - University of Torino
  - | Location: Hall A (Poster Board #345)
  - | Poster Discussion Session: Saturday, June 3, 2017; 3:00-4:15 p.m. CDT, Hall D2

## **Galunisertib**

- | Abstract #4097: Gastrointestinal (Noncolorectal) Cancer: Saturday, June 3, 2017; 8:00-11:30 a.m. CDT
  - | A Phase 2 study of galunisertib (TGF- $\beta$  R1 inhibitor) and sorafenib in patients with advanced hepatocellular carcinoma (HCC)
  - | Author/Speaker: Robin Kate Kelley, M.D., University of California, San Francisco
  - | Location: Hall A (Poster Board #89)

- | Abstract #1064: Breast Cancer—Metastatic: Sunday, June 4, 2017; 8:00-11:30 a.m. CDT
  - | Safety and tolerability of the dual PI3K/mTOR inhibitor LY3023414 in combination with fulvestrant in treatment refractory advanced breast cancer patients
  - | Author/Speaker: Anna M. Varghese, M.D., Memorial Sloan-Kettering Cancer Center
  - | Location: Hall A (Poster Board #56)

#### **LY3009120**

- | Abstract #2507: Oral Presentation: Developmental Therapeutics—Clinical Pharmacology and Experimental Therapeutics: Saturday, June 3, 2017; 1:15-4:15 p.m. CDT
  - | A first-in-human dose Phase 1 study of LY3009120 in advanced cancer patients
  - | Author/Speaker: David S. Hong, M.D., The University of Texas MD Anderson Cancer Center
  - | Location: E450ab

#### **LY3022855**

- | Abstract #2523: Developmental Therapeutics—Clinical Pharmacology and Experimental Therapeutics: Monday, June 5, 2017; 8:00-11:30 a.m. CDT
  - | A Phase 1 study of LY3022855, a colony-stimulating factor-1 receptor (CSF-1R) inhibitor, in patients (pts) with advanced solid tumors
  - | Author/Speaker: Afshin Dowlati, M.D., University Hospitals Seidman Cancer Center, Case Comprehensive Cancer Center, Case Western Reserve University
  - | Location: Hall A (Poster Board #15)

#### **LY3039478**

- | Abstract #6024: Head and Neck Cancer: Monday, June 5, 2017; 1:15-4:45 p.m. CDT
  - | Notch pathway inhibition with LY3039478 in adenoid cystic carcinoma (ACC)
  - | Author/Speaker: Caroline Even, Institut Gustave Roussy
  - | Location: Hall A (Poster Board #12)
  - | Poster Discussion Session: Monday, June 5, 2017; 4:45-6:00 p.m. CDT, S406

#### **Notes to Editor**

##### **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](http://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](http://www.lilly.com) and [www.lilly.com/newsroom/social-channels](http://www.lilly.com/newsroom/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 United States Private Securities Litigation Reform Act of 1995) regarding Lilly's oncology portfolio and pipeline, including abemaciclib, emibetuzumab, fruquintinib, olaratumab, pemetrexed, ramucirumab, galunisertib, LY3023414, LY3009120, LY3022855, and LY3039478. This press release reflects Lilly's current beliefs. However, there are substantial risks and uncertainties in the process of drug research, 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 that could cause actual results to differ materially from Lilly's expectations, please see the company's latest Forms 10-K and 10-Q filed with the U.S. Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements.*

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To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/lilly-to-present-results-from-pivotal-breast-cancer-study-of-abemaciclib-and-new-portfolio-data-at-asco-2017-300459622.html>

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