



August 29, 2017

New Phase 3 Data for Abemaciclib and Ramucirumab Presented at ESMO 2017 Congress

First presentations of MONARCH 3, a Phase 3 study of abemaciclib as initial treatment for advanced breast cancer, and RANGE, a Phase 3 study of ramucirumab for the treatment of platinum-refractory urothelial cancer

INDIANAPOLIS, Aug. 29, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) will showcase new data across six different tumor types at the European Society for Medical Oncology (ESMO) 2017 Congress in Madrid, Spain, September 8-12, 2017. Notably, results from Phase 3 studies of abemaciclib and ramucirumab have been selected for oral presentation during a Presidential Symposium, which features groundbreaking research that is potentially practice-changing, on September 10.

"In line with this year's theme of 'integrating science into oncology for a better patient outcome,' the data being presented at ESMO demonstrate how we are further developing our foundational medicines - each rooted in the biology of cancer - to deliver innovative breakthrough medicines that will make a meaningful difference to patients and doctors," said Levi Garraway, M.D., Ph.D., senior vice president, global development and medical affairs, Lilly Oncology. "We are excited to share new data that shows our progress on bringing forward abemaciclib as a potential new treatment option for advanced breast cancer and investigating the use of ramucirumab in additional tumor types such as advanced or metastatic urothelial carcinoma."

For the first time, two Lilly molecules will be featured in an ESMO Presidential Symposium, with data from its MONARCH 3 and RANGE studies in advanced breast cancer and platinum-refractory urothelial cancer, respectively. MONARCH 3 is a global Phase 3, double-blind, placebo-controlled study, which evaluated the efficacy and safety of abemaciclib in combination with a nonsteroidal aromatase inhibitor (letrozole or anastrozole) as initial endocrine-based therapy for postmenopausal women with advanced breast cancer who have had no prior systemic treatment for advanced disease. RANGE is a global Phase 3 randomized, double-blind study evaluating the safety and efficacy of ramucirumab and docetaxel compared to placebo and docetaxel in patients with advanced or metastatic urothelial carcinoma whose disease progressed on or after platinum-based chemotherapy.

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

Abemaciclib

- | Abstract Title: MONARCH 3: Abemaciclib as initial therapy for patients with HR+/HER2- advanced breast cancer
 - | Abstract #236O_PR; Presidential Symposium II: Sunday, September 10, 2017; 16:30-16:45 CEST
 - | Author/Speaker: Angelo Di Leo, M.D., Hospital of Prato, Instituto Toscano Tumori
 - | Location: Madrid Auditorium

- | Abstract Title: Efficacy and Safety of Abemaciclib Combined with LY3023414 or Pembrolizumab in Stage IV NSCLC
 - | Abstract #1363P; Poster Session: Saturday, September 9, 2017; 13:15-14:15 CEST
 - | Author/Speaker: Pilar Garrido Lopez, M.D., Hospital Universitario Ramón y Cajal
 - | Location: Hall 8

- | Abstract Title: Analysis of overall survival by tumor response in MONARCH 1, a phase 2 study of abemaciclib, a CDK4 and CDK6 inhibitor, in women with HR+/HER2- metastatic breast cancer (MBC) after chemotherapy for advanced disease
 - | Abstract #249P; Poster Session: Monday, September 11, 2017; 13:15-14:15 CEST
 - | Author/Speaker: Javier Cortés, M.D., Vall d'Hebron University Hospital
 - | Location: Hall 8

- | Abstract Title: Abemaciclib plus fulvestrant in patients (pts) with HR+/HER2- endocrine therapy naïve (EN) advanced breast cancer - an exploratory analysis of MONARCH 2
 - | Abstract #253P; Poster Session: Monday, September 11, 2017; 13:15-14:15 CEST
 - | Author/Speaker: Peter Kaufman, M.D., Dartmouth-Hitchcock Medical Center
 - | Location: Hall 8

Ramucirumab

- | Abstract Title: RANGE: a randomized, double-blind, placebo-controlled phase 3 study of docetaxel (DOC) with or without ramucirumab (RAM) in platinum-refractory advanced or metastatic urothelial carcinoma
 - | Abstract #LBA4; Presidential Symposium II: Sunday, September 10, 2017; 17:30-17:45 CEST
 - | Author/Speaker: Daniel Petrylak, M.D., Yale Cancer Center
 - | Location: Madrid Auditorium

- | Abstract Title: Meta-analysis of individual patient safety data from six randomized, placebo-controlled trials with the antiangiogenic VEGFR2-binding monoclonal antibody ramucirumab
 - | Abstract #1592P; Poster Session: Sunday, September 10, 2017; 13:15-14:15 CEST
 - | Author/Speaker: Dirk Arnold, M.D., Klinik für Tumoriologie
 - | Location: Hall 8

- | Abstract Title: A Dose-Response Study of Ramucirumab Treatment in Patients with Gastric Cancer/Gastroesophageal Junction Adenocarcinoma: Primary Results of 4 Dosing Regimens in the Phase 2 Trial I4T-MC-JVDB
 - | Abstract #698P; Poster Session: Saturday, September 9, 2017; 13:15-14:15 CEST
 - | Author/Speaker: Jaffer Ajani, M.D., MD Anderson Cancer Center
 - | Location: Hall 8

- | Abstract Title: Analysis of Angiogenesis Biomarkers for Ramucirumab (RAM) Efficacy in Patients with Metastatic Colorectal Cancer (mCRC) from RAISE, a Global, Randomized, Double-Blind, Phase 3 Study
 - | Abstract #555P; Poster Session: Saturday, September 9, 2017; 13:15-14:15 CEST
 - | Author/Speaker: Josep Tabernero, M.D., Vall d'Hebron University Hospital
 - | Location: Hall 8

Sarcoma

- | Abstract Title: The Sarcoma Policy Checklist - focusing policy efforts on sarcoma
 - | Abstract #1493P; Poster Session: Monday, September 11, 2017; 13:15-14:15 CEST
 - | Author/Speaker: Bernd Kasper, M.D., Universitätsmedizin Mannheim
 - | Location: Hall 8

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.

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 www.lilly.com/newsroom/social-channels. 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 abemaciclib as a potential treatment for patients with breast cancer and ramucirumab as a potential treatment for patients with treatment of platinum-refractory urothelial cancer, and reflects Lilly's current beliefs. However, as with any pharmaceutical products, 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 abemaciclib or ramucirumab 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.

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