Lilly to Present New Data From Oncology Portfolio at ESMO 2018 Congress, Showcasing Patient-Centric Advances in Cancer Care

October 8, 2018

Data from abemaciclib, pemetrexed and ramucirumab late-stage clinical development programs in multiple difficult-to-treat tumor types

New data for pegilodecakin used as a single agent and in combination with chemotherapy and with checkpoint inhibitor therapy

INDIANAPOLIS, Oct. 8, 2018 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) will present new data from its clinical development program at the European Society for Medical Oncology (ESMO) 2018 Congress in Munich, Germany, October 19-23. Data presented showcase how Lilly is taking a global, patient-centric research approach to drive advances in cancer care. Data include presentations on abemaciclib, pemetrexed and ramucirumab, as well as investigational compound pegilodecakin – used as a single agent and in combination with chemotherapy and with checkpoint inhibitor therapy – across multiple tumor types. Pegilodecakin joined the Lilly Oncology pipeline with the company's acquisition of ARMO BioSciences earlier this year.

Key abemaciclib data include findings from the Phase 3 MONARCH 2 trial evaluating abemaciclib plus fulvestrant in women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced breast cancer. Additionally, results will be presented from Lilly's ongoing immuno-oncology clinical collaboration with Merck (known as MSD outside the U.S. and Canada) on the KEYNOTE-189 trial evaluating pemetrexed plus platinum chemotherapy in combination with pembrolizumab in the first-line treatment of metastatic nonsquamous non-small cell lung cancer (NSCLC). Ramucirumab data include Phase 3 findings from several patient populations with aggressive disease such as the REACH-2 study of ramucirumab as a single agent in the second-line treatment of people with hepatocellular carcinoma (HCC), also known as liver cancer, and the RANGE study evaluating ramucirumab in combination with docetaxel in patients with locally advanced or unresectable or metastatic urothelial carcinoma whose disease progressed on or after platinum-based chemotherapy. Pegilodecakin data include new results from an early-phase study in patients with renal cell, non-small cell lung, pancreatic, ovarian and breast cancers.

"The breadth and depth of our data being presented at ESMO underscores this year's congress theme of 'securing access to optimal cancer care' by demonstrating how we are working to develop innovative new medicines that will make a difference to patients and doctors," said Maura Dickler, M.D., vice president, late phase development, Lilly Oncology. "We're also excited to share data for the first time from our promising next generation clinical immunotherapy asset pegilodecakin, which examines its potential in several tumor types in combination with existing treatments and as a monotherapy. We are encouraged by the results and look forward to further investigating pegilodecakin in a wide range of settings."

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

Abemaciclib

Abstract #329P: Abemaciclib with fulvestrant in patients with HR+, HER2- advanced breast cancer (ABC) that exhibited primary or secondary resistance to prior endocrine therapy (ET)

- Monday, October 22; 12:45-1:45 p.m. CEST; Exhibit Hall A3

Abstract #339P: Management of abemaciclib associated adverse events in patients with hormone receptor positive (HR+), HER2- advanced breast cancer: analysis of the MONARCH trials

- Monday, October 22; 12:45-1:45 p.m. CEST; Exhibit Hall A3

Pegilodecakin

Abstract #1130O: Responses and Durability of Clinical Benefit in Renal Cell Carcinoma Treated with Pegilodecakin in Combination with Anti-PD-1 Inhibitors

- Monday, October 22; 12:18-12:30 p.m. CEST; Exhibit Hall A2 – Room 18

Abstract #1145P: Responses and Durability of Cinical Benefit in Triple Negative Breast Cancer Patients Treated With Pegilodecakin Monotherapy or in Combination With Platinum Plus Taxane-Based Chemotherapy

- Saturday, October 20; 12:30-1:30 p.m. CEST; Exhibit Hall A3

Abstract #1144P: Responses and Durability of Clinical Benefit in Non-Small Cell Lung Cancer Treated with Pegilodecakin in Combination With Anti-PD-1 Inhibitors

- Saturday, October 20; 12:30-1:30 p.m. CEST; Exhibit Hall A3

Abstract #1143P: Responses and Durability of Clinical Benefit in Pancreatic Ductal Adenocarcinoma (PDAC) Patients Treated With Pegilodecakin (AM0010) in Combination With 5-FU/LV and Oxaliplatin (FOLFOX)

- Saturday, October 20; 12:30-1:30 p.m. CEST; Exhibit Hall A3

Abstract #1146P: Durability of Clinical Benefit in Metastatic Epithelial Ovarian Cancer Patients Treated With Pegilodecakin Monotherapy or in Combination With Platinum Plus Taxane-Based Chemotherapy

- Saturday, October 20; 12:30-1:30 p.m. CEST; Exhibit Hall A3

Abstract #1180P: Combination of Pegilodecakin and Docetaxel Shows Synergy in Tumor Rejection in Immune Resistant TNBC model

- Saturday, October 20; 12:30-1:30 p.m. CEST; Exhibit Hall A3

Pemetrexed

Abstract #1464P: KEYNOTE-189 study of pembrolizumab (pembro) plus pemetrexed (pem) and platinum vs placebo plus pem and platinum for untreated, metastatic, nonsquamous NSCLC: does choice of platinum affect outcomes?

- Saturday, October 20; 12:30-1:30 p.m. CEST; Exhibit Hall A3

Abstract #1381PD: Gefitinib With or Without Pemetrexed in Nonsquamous (NS) Non-Small Cell Lung Cancer (NSCLC) With EGFR Mutation (mut): Final Overall Survival (OS) Results From a Randomized Phase II Study

- Friday, October 19; 2:00-4:00 p.m. CEST; ICM – Room 14b

Ramucirumab

Abstract #622PD: Ramucirumab as second-line treatment in patients with advanced hepatocellular carcinoma (HCC) and elevated alpha-fetoprotein (AFP) following first-line sorafenib: patient reported outcome results across two phase 3 studies (REACH-2 and REACH)

- Friday, October 19; 3:45-5:25 p.m. CEST; ICM – Exhibit Hall B3 – Room 21

Abstract #708P: Relationship between change in α-fetoprotein (AFP) and patient (pt) survival in hepatocellular carcinoma (HCC): a real-world electronic medical records (EMR) database study

- Sunday, October 21; 12:45-1:45 p.m. CEST; Exhibit Hall A3

Abstract #865PD: RANGE, a phase 3, randomized, placebo-controlled, double-blind trial of ramucirumab (RAM) and docetaxel (DOC) in platinum-refractory urothelial carcinoma (UC): overall survival results

- Saturday, October 20; 2:45-4:05 p.m. CEST; ICM – Room 1

Abstract #616PD: Quality-of-life (QoL) results from RAINFALL: A randomized, double-blind, placebo (PL)-controlled phase 3 study of cisplatin (Cis) plus capecitabine (Cape) or 5FU with or without ramucirumab (RAM) as first-line therapy for metastatic gastric or gastroesophageal junction (G-GEJ) cancer

- Friday, October 19; 3:45-5:30 p.m. CEST; Exhibit Hall B3 – Room 21

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 newsroom.lilly.com/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) regarding Lilly's oncology portfolio and pipeline, including abemaciclib, pegilodecakin, pemetrexed and ramucirumab. 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 they will achieve intended benefits or become commercially successful products. 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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