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# ASCO Data Underscore Lilly's Diverse Oncology Pipeline and Portfolio

## Final phase 2 monotherapy data on CDK 4 and 6 inhibitor abemaciclib in metastatic breast cancer to be featured in oral presentation

INDIANAPOLIS, May 18, 2016 /PRNewswire/ -- Several studies will underscore the strength of Eli Lilly and Company's (NYSE: LLY) diverse clinical cancer pipeline and portfolio during the 52nd Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, June 3 - 7, 2016. Presentations include new data on abemaciclib, a CDK 4 and 6 inhibitor, as well as: ramucirumab, a VEGF Receptor 2 antagonist; galunisertib, a TGFβ small-molecule kinase inhibitor; and emibetuzumab, a MET antibody.

Other data to be presented at ASCO highlight Lilly's ongoing immuno-oncology clinical collaborations with Merck (known as MSD outside the U.S. and Canada) in two trials that are evaluating ramucirumab and pemetrexed-plus-carboplatin, respectively, in combination with Merck's pembrolizumab.

These presentations reflect Lilly's multi-faceted strategy in developing cancer treatments - a balanced approach based on three scientific pillars of tumor cell growth and progression: cell signaling, tumor microenvironment and immuno-oncology. Lilly's data at this year's ASCO meeting highlight some of the recent progress it has made toward this strategy and touch on all three of these scientific pillars.

"The reality is that cancer is more than 200 diseases and the treatment of cancer needs to be aggressively approached from many angles," said Richard Gaynor, M.D., senior vice president, product development and medical affairs for Lilly Oncology. "Our oncology R&D strategy is to produce a diverse portfolio of novel agents that attack tumor cell growth and progression in multiple ways to improve patient outcomes."

Dr. Gaynor continued, "We are encouraged by our data at ASCO and the progress of our pipeline toward achieving our overall goals. We've had notable clinical advancements with abemaciclib and olaratumab, both of which have been designated as breakthrough therapies by the FDA. These build on necitumumab and ramucirumab, which we are continuing to investigate in additional disease settings and combinations. Additionally, our immuno-oncology initiatives are increasingly producing results through collaborations and our own internal research efforts."

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

**Abemaciclib**

- Abstract #510: Oral Abstract Session: Friday, June 3, 2016; 4:42 - 4:54 pm CDT
  - MONARCH 1: Results from a phase 2 study of abemaciclib, a CDK4 and CDK6 inhibitor, as monotherapy, in patients with HR+/HER2- breast cancer, after chemotherapy for advanced disease
  - Author/Speaker: Maura N. Dickler, M.D., Memorial Sloan Kettering Cancer Center
  - Location: Hall D1

- Abstract #TPS9101: Lung Cancer—Non-Small Cell Metastatic Poster Session: Saturday, June 4, 2016; 8:00 - 11:30 am CDT
  - A randomized phase 2 study of abemaciclib versus docetaxel in patients with stage IV squamous cell lung cancer (SqCLC) previously treated with platinum-based chemotherapy
  - Author/Speaker: Giorgio V. Scagliotti, M.D., Ph.D., University of Torino
  - Location: Hall A (Poster Board #423a)

**Immuno-Oncology Collaborations with ramucirumab or pemetrexed**

- Abstract #3056: Developmental Therapeutics—Immunotherapy Poster Session: Sunday, June 5, 2016; 8:00 - 11:30 am CDT
  - A phase 1 study of ramucirumab (R) plus pembrolizumab (P) in patients (pts) with advanced gastric or gastroesophageal junction (G/GEJ) adenocarcinoma, non-small cell lung cancer (NSCLC), or urothelial

carcinoma (UC): Phase 1a results
    - Author/Speaker: Roy S. Herbst, M.D., Ph.D., Yale University School of Medicine, Yale Cancer Center
    - Location: Hall A (Poster Board #378)

- Abstract #9016: Lung Cancer—Non-Small Cell Metastatic Poster Session: Saturday, June 4, 2016; 8:00 - 11:30 am CDT
    - Pembrolizumab (pembro) plus chemotherapy as front-line therapy for advanced NSCLC: KEYNOTE-021 cohorts A-C
    - Author/Speaker: Shirish M. Gadgeel, M.D., Karmanos Cancer Institute
    - Location: Hall A (Poster Board #339)
    - Poster Discussion Session: Saturday, June 4, 2016; 3:00 - 4:15 pm CDT Room E354b

**Ramucirumab**

- Abstract #TPS4145: Gastrointestinal (Noncolorectal) Cancer Poster Session: Saturday, June 4, 2016; 8:00 - 11:30 am CDT
    - A randomized, double-blind, placebo-controlled Phase III study of ramucirumab versus placebo as second-line treatment in patients with hepatocellular carcinoma and elevated baseline alpha-fetoprotein following first-line sorafenib (REACH-2)
    - Author/Speaker: Andrew X. Zhu, M.D., Ph.D., Massachusetts General Hospital Cancer Center
    - Location: Hall A (Poster Board #130a)

- Abstract #9079: Lung Cancer—Non-Small Cell Metastatic Poster Session: Saturday, June 4, 2016; 8:00 - 11:30 am CDT
    - Exploratory subgroup analysis of patients (Pts) refractory to first-line (1L) chemotherapy from REVEL, a randomized phase III study of docetaxel (DOC) with ramucirumab (RAM) or placebo (PBO) for second-line (2L) treatment of stage IV non-small-cell lung cancer (NSCLC)
    - Author/Speaker: Martin Reck, M.D., Ph.D., Lungen Clinic Grosshansdorf, Airway Research Center North
    - Location: Hall A (Poster Board #402)

**Galunisertib**

- Abstract #4070: Gastrointestinal (Noncolorectal) Cancer Poster Session: Saturday, June 4, 2016; 8:00 - 11:30 am CDT
    - A phase 2 study of galunisertib, a novel transforming growth factor-beta (TGF-β) receptor I kinase inhibitor, in patients with advanced hepatocellular carcinoma (HCC) and low serum alpha fetoprotein (AFP)
    - Author/Speaker: Sandrine J. Faivre, M.D., Ph.D., Service d'Oncologie Médicale
    - Location: Hall A (Poster Board #62)

- Abstract #4019: Gastrointestinal (Noncolorectal) Cancer Poster Session: Saturday, June 4, 2016; 8:00 - 11:30 am CDT
    - A phase II, double-blind study of galunisertib+gemcitabine (GG) vs gemcitabine+placebo (GP) in patients (pts) with unresectable pancreatic cancer (PC)
    - Author/Speaker: Davide Melisi, M.D., University of Verona
    - Location: Hall A (Poster Board #11)
    - Poster Discussion Session: Saturday, June 4, 2016; 3:00 - 4:15 pm CDT at Hall D1

**Emibetuzumab**

- Abstract #9070: Lung Cancer—Non-Small Cell Metastatic Poster Session: Saturday, June 4, 2016; 8:00 - 11:30 am CDT
    - A randomized, open-label, phase 2 study of emibetuzumab plus erlotinib (LY+E) and emibetuzumab monotherapy (LY) in patients with acquired resistance to erlotinib and MET diagnostic positive (MET Dx+) metastatic NSCLC
    - Author/Speaker: D. Ross Camidge, M.D., Ph.D., University of Colorado
    - Location: Hall A (Poster Board #393)

**About Lilly Oncology**
For more than fifty 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.

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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, galunisertib, necitumumab, olaratumab, pemetrexed and ramucirumab. 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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