October 5, 2016

Lilly Highlights Advancements in its Oncology Portfolio with New Data at ESMO 2016

INDIANAPOLIS, Oct. 5, 2016 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) will present data from several studies which further reinforce the advancement of its diverse clinical cancer portfolio during the European Society of Medical Oncology's (ESMO) 2016 Congress in Copenhagen, October 7-11. Presentations include new data on abemaciclib, a CDK 4 and CDK 6 inhibitor, and olaratumab, a PDGFRα blocking antibody that recently received a positive CHMP opinion, as well as data on: pemetrexed, a multi-targeted antifolate; ramucirumab, a VEGF Receptor 2 antagonist; necitumumab, an EGFR blocking antibody; and prexasertib, a cell cycle checkpoint kinases 1 and 2 inhibitor. Of these presentations, four are featured in late-breaking abstracts (two on abemaciclib, and one each on pemetrexed and ramucirumab).

The presentations on pemetrexed, ramucirumab and necitumumab include data from a few of Lilly's immuno-oncology clinical collaborations with Merck (known as MSD outside the U.S. and Canada) in trials that are evaluating these molecules in combination with Merck's pembrolizumab. Notably, the first results from KEYNOTE-021G - which studied pembrolizumab in combination with pemetrexed-plus-carboplatin compared to pemetrexed-plus-carboplatin alone for the first-line treatment of patients with advanced nonsquamous non-small cell lung cancer regardless of PD-L1 expression - will be featured in the Presidential Symposium on October 9.

Lilly's data at the ESMO 2016 Congress highlight the ongoing progress in expanding the potential of its portfolio molecules as well as the advancement of its clinical pipeline. These presentations underscore the company's multi-faceted strategy in developing cancer treatments - to produce a diverse portfolio of novel agents that attack tumor cell growth and progression in multiple ways to improve patient outcomes. Specifically, this is a balanced approach based on three scientific pillars of tumor cell growth and progression:

- Tumor cell signaling: Therapies that target cell signaling to interrupt the communication system that enables cancer cells to coordinate their basic activities;
- Tumor microenvironment: Treatments attacking the tumor microenvironment which work by reducing the flow of nutrients and mitogens that support and feed tumor cells; and
- Immuno-oncology: Therapies that use the patient's own immune system to fight cancer.

"Lilly's three-pillar oncology R&D strategy is unique," said Richard Gaynor, M.D., senior vice president, product development and medical affairs for Lilly Oncology. "While there's no single therapy or one way to attack tumor cell growth and progression that works for all patients, as an industry we are continually learning how some approaches work better than others in certain patient populations. Lilly is aggressively approaching cancer therapy development from many angles, including the study of combination therapies across the three pillars to address tumor heterogeneity and drug resistance, through our own efforts and research collaborations. Data to be presented at this year's ESMO Congress demonstrate our intent to bring forth best-in-class treatment options to help patients around the world."

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

Abemaciclib

- Abstract Title: Interim results from neoMONARCH: a neoadjuvant phase II study of abemaciclib in postmenopausal women with HR+/HER2- breast cancer (BC)
  - Abstract #: LBA13; Proffered Paper session: Friday, October 7, 16:00 - 17:30 CEST
  - Author/Speaker: Sara Hurvitz, M.D., UCLA Jonsson Comprehensive Cancer Center
  - Location/Room: Stockholm
- Abstract Title: Exploratory biomarkers in MONARCH 1, a phase II study of abemaciclib monotherapy in hormone-receptor positive (HR+) HER2- metastatic breast cancer (MBC)
  - Abstract #: LBA12; Poster Discussion session: Sunday, October 9, 16:30 - 17:30 CEST
  - Author/Speaker: Sara M. Tolaney, M.D., MPH, Dana-Farber Cancer Institute
  - Location/Room: Berlin

Immuno-Oncology Collaborations with Pemetrexed, Ramucirumab and Necitumumab

- Abstract Title: Randomized, phase 2 study of carboplatin and pemetrexed with or without pembrolizumab as first-line

therapy for advanced NSCLC: KEYNOTE-021 cohort G
    - Abstract #: LBA46_PR; Presidential Symposium session: Sunday, October 9, 16:25 - 18:20 CEST
    - Author/Speaker: Corey Langer, M.D., University of Pennsylvania
    - Location/Room: Copenhagen
- Abstract Title: Interim safety and clinical activity in patients with advanced NSCLC from a multi-cohort phase 1 study of ramucirumab (R) plus pembrolizumab (P)
    - Abstract #: LBA38; Poster Discussion session: Monday, October 10, 09:30 - 10:30 CEST
    - Author/Speaker: Roy S. Herbst, M.D., Ph.D., Yale Cancer Center
    - Location/Room: Berlin
- Abstract Title: Safety of necitumumab and pembrolizumab combination therapy in patients with stage IV non-small cell lung cancer (NSCLC): A phase 1b expansion cohort study
    - Abstract #: 1260P; Poster Display session: Saturday, October 8, 13:00 - 14:00 CEST
    - Author/Speaker: Benjamin Besse, M.D., Ph.D., Institut d'Oncologie Thoracique
    - Location/Room: Hall E

Olaratumab

- Abstract Title: Exposure-response of olaratumab for survival outcomes and safety when combined with doxorubicin in soft tissue sarcoma (STS) patients
    - Abstract #: 1402PD; Poster Discussion session: Monday, October 10, 11:00 - 12:00 CEST
    - Author/Speaker: Robin L. Jones, BSc, MB, MRCP, M.D., Fred Hutchinson Cancer Research Center
    - Location/Room: Brussels
- Abstract Title: ANNOUNCE 2: An open-label phase 1b, and a randomized, double-blind phase 2 study of olaratumab with gemcitabine plus docetaxel in the treatment of patients with advanced soft tissue sarcoma (STS)
    - Abstract #: 1420TiP; Poster Display session: Monday, October 10, 13:00 - 14:00 CEST
    - Author/Speaker: Andrés Redondo, M.D., Hospital Universitario La Paz
    - Location/Room: Hall E

Prexasertib

- Abstract Title: A phase II study of the cell cycle checkpoint kinases 1 and 2 inhibitor (LY2606368; Prexasertib monomesylate monohydrate) in sporadic high-grade serous ovarian cancer (HGSOC) and germline BRCA mutation-associated ovarian cancer (gBRCAm+ OvCa)*
    - Abstract #: 855O; Proffered Paper session: Friday, October 7, 14:00 - 15:30 CEST
    - Author/Speaker: Jung-min Lee, M.D., Center for Cancer Research, National Cancer Institute, National Institutes of Health
    - Location/Room: Oslo

Ramucirumab

- Abstract Title: Ramucirumab (RAM) as a second-line treatment in patients (pts) with advanced hepatocellular carcinoma (HCC): Prognosis, efficacy, and safety by liver disease etiology
    - Abstract #: 617PD; Poster Discussion session: Saturday, October 8, 08:00 - 09:00 CEST
    - Author/Speaker: Takuji Okusaka, M.D., National Cancer Center Hospital
    - Location/Room: Copenhagen
- Abstract Title: 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)
    - Abstract #: 710TiP; Poster Display session: Saturday, October 8, 13:00 - 14:00 CEST
    - Author/Speaker: Andrew X. Zhu, M.D., Ph.D., Massachusetts General Hospital Cancer Center
    - Location/Room: Hall E

**This presentation on prexasertib includes data from an investigator-initiated trial sponsored by the Center for Cancer Research, National Cancer Institute (NCI), part of the National Institutes of Health.*

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 United States Private Securities Litigation Reform Act of 1995) regarding Lilly's oncology portfolio, including abemaciclib, necitumumab, olaratumab, pemetrexed, prexasertib 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 they 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-highlights-advancements-in-its-oncology-portfolio-with-new-data-at-esmo-2016-300339515.html

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