PRESS RELEASE

Eli Lilly Sweden AB

Gustav III Boulevard 42
Frösundavik I Solna
Postadress: Box 721
16927 Solna
Telefon vxl: +46(0)737 88 00

www.lilly.se

VERZENIOS® MINSKAR SIGNIFIKANT RISKEN FÖR ÅTERFALL VID TIDIG HORMONRECEPTORPOSITIV OCH HER2-NEGATIV BRÖSTCANCER HOS PATIENTER MED HÖG RISK

Verzenios® (abemaciklib) i kombination med standard endokrin (antihormonell) behandling visar på en statistiskt signifikant förlängd invasiv sjukdomsfriöverlevnad (IDFS) vid tidig hormonreceptorpositiv, HER2-negativ bröstcancer. Risken för återfall minskade med 25 procent.

Fas 3-studien monarchE som utvärderade effekten av två års behandling med abemaciklib som tillägg till standard endokrin behandling uppnådde det primära effektmåttet invasiv sjukdomsfriöverlevnad (IDFS) hos patienter med hormonreceptorpositiv, HER2-negativ bröstcancer med hög risk för återfall.

Resultaten presenterades vid "Presidential Symposium" vid årets virtuella ESMO-kongress, European Society for Medical Oncology, den 20 september 2020, och publicerades samtidigt i the Journal of Clinical Oncology (JCO).

SUNDAY, September 20, 2020 – Eli Lilly and Company today announced Verzenios® (abemaciclib) in combination with standard adjuvant endocrine therapy (ET) significantly decreased the risk of breast cancer recurrence by 25 percent compared to standard adjuvant ET alone for people with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) high risk early breast cancer (HR: 0.747; 95% CI: 0.598, 0.932; p = 0.0096). This statistically significant benefit was consistent across all pre-specified subgroups and corresponds to a 3.5 percent difference between arms (92.2 percent in the abemaciclib arm and 88.7 percent in the control arm) at two years. These results are from a preplanned interim analysis with 323 IDFS events observed in the intent-to-treat population across both arms, including 136 in the abemaciclib arm and 187 in the control arm. The data were presented today in the Presidential Symposium at the European Society for Medical Oncology (ESMO) 2020 Virtual Congress and simultaneously published in the *Journal of Clinical Oncology*.

PRESS RELEASE

Eli Lilly Sweden AB

Gustav III Boulevard 42
Frösundavik I Solna
Postadress: Box 721
16927 Solna
Telefon vxl: +46(0)737 88 00

www.lilly.se

Safety data from monarchE were consistent with the known safety profile of abemaciclib and no new safety signals were observed. At the time of analysis, approximately 70 percent of patients in each arm were still on the two-year treatment period. The median follow up was approximately 15.5 months in both arms. The median duration on abemaciclib was 14 months.

monarchE randomised 5,637 patients with HR+, HER2- high risk early breast cancer from more than 600 sites in 38 countries. High risk was defined by spread to the lymph nodes, a large tumour size, or high cellular proliferation (as determined by tumour grade or Ki-67 index). Patients were treated for two years (treatment period) or until meeting criteria for discontinuation. After the treatment period, all patients will continue ET for five to 10 years, as clinically indicated.

"We are excited that abemaciclib has demonstrated a clinically meaningful reduction in the risk of recurrence for people with HR+, HER2- high risk early breast cancer, and Lilly would like to thank the patients and investigators around the world who made this trial possible," said Maura Dickler, M.D., vice president, late phase development, Lilly Oncology. "The results on invasive disease-free survival are significant and provide hope for people with high risk early breast cancer living with concerns of recurrence. Lilly will submit these results to regulatory bodies around the world as soon as possible and we look forward to being able to offer abemaciclib as a new treatment option for these patients. We are proud of the way monarchE builds on the vast body of clinical evidence established for abemaciclib."

The addition of abemaciclib to endocrine therapy also resulted in an improvement in distant relapse-free survival, or the time to developing cancer that has spread to other parts of the body. The combination reduced the risk of developing metastatic disease by 28 percent (HR: 0.717; 95% CI: 0.559, 0.920), with the largest reductions occurring in rates of metastases to the liver and bone. This treatment benefit was consistent across all prespecified subgroups. Two-year distant relapse-free survival rates were 93.6 percent in the abemaciclib arm and 90.3 percent in the control arm.

Overall survival results were immature and monarchE will continue through the completion date, estimated for June 2027. At the time of the interim analysis, the IDFS results are considered definitive. All patients on monarchE will be followed until primary analysis and beyond to assess

Eli Lilly Sweden AB

Gustav III Boulevard 42
Frösundavik I Solna
Postadress: Box 721
16927 Solna
Telefon vxl: +46(0)737 88 00

www.lilly.se

overall survival and other endpoints. Lilly will submit the monarchE data to regulatory authorities before the end of 2020.

About the monarchE Study

monarchE is a Phase 3, multi-centre, randomised, open-label trial that enrolled 5,637 patients with HR+, HER2- node-positive, high risk early breast cancer. Patients were randomised 1:1 to abemaciclib (150 mg twice daily) plus standard adjuvant endocrine therapy or standard adjuvant endocrine therapy alone. Patients were treated for two years (treatment period) or until meeting criteria for discontinuation. After the treatment period, all patients will continue on endocrine therapy for five to 10 years, as clinically indicated. The primary objective is invasive disease-free survival (IDFS) defined according to the Standard Definitions for Efficacy Endpoints (STEEP) criteria. In adjuvant breast cancer trials, this includes the length of time before any cancer comes back, a new cancer develops or death. Secondary objectives include distant relapse-free survival, overall survival, safety, pharmacokinetics and health outcomes.

High risk was specifically defined as women (any menopausal status) and men with resected HR+, HER2- invasive early breast cancer with either ≥4 pathologically positive axillary lymph nodes (ALNs) or 1 to 3 positive ALNs and at least one of the following high-risk features: primary invasive tumour size ≥5 cm, histological grade 3 tumour, or central Ki-67 index ≥20%. If applicable, patients must have also completed adjuvant chemotherapy and radiotherapy prior to enrolling and have recovered from all acute side effects.

About Early Breast Cancer

Breast cancer is the most common cancer among women worldwide.[i] An estimated 90 percent of all breast cancer is diagnosed at an early stage.[ii] Approximately 70 percent of all breast cancers are HR+, HER2-, the most common subtype.[iii] The term 'early breast cancer' describes cancer that has not spread from the breast to another part of the body.[iv] Even within this subtype, HR+, HER2- breast cancer is a complex disease, and many factors – such as if the cancer has spread to the lymph nodes and the biology of the tumour – can impact the risk of recurrence. Approximately 30 percent of people diagnosed with HR+ early breast cancer are at risk of their cancer returning, potentially to incurable metastatic disease.[v]

PRESS RELEASE

Eli Lilly Sweden AB

Gustav III Boulevard 42
Frösundavik I Solna
Postadress: Box 721
16927 Solna
Telefon vxl: +46(0)737 88 00

www.lilly.se

About Verzenios® (abemaciclib)

Abemaciclib is an inhibitor of cyclin-dependent kinases (CDK)4 & 6, which are activated by binding to D-cyclins. In estrogen receptor-positive (ER+) breast cancer cell lines, cyclin D1 and CDK4 & 6promote phosphorylation of the retinoblastoma protein (Rb), cell cycle progression, and cell proliferation.

Abemaciclib is indicated for the treatment of HR+, HER2- advanced or metastatic breast cancer:

- in combination with an aromatase inhibitor for postmenopausal women as initial endocrine-based therapy
- in combination with fulvestrant for women with disease progression following endocrine therapy

- ENDS -

To arrange an interview or for further information please contact:
Media contact: Sarah Davies Lilly UK Press Office
Phone: +44 (0)1256 775374
Email: ukpublicaffairs@lilly.com

Notes to Editors

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.co.uk**

---

[i] World Health Organization. Breast cancer: prevention and control. https://www.who.int/cancer/detection/breastcancer/en/index1.html. Accessed: September 8, 2020.

[ii] Howlader N, et al. SEER Cancer Statistics Review, 1975-2013. http://seer.cancer.gov/csr/1975_2013/. Accessed: September 8, 2020.

[iii] Howlader N, Altekruse S, Li C. US incidence of breast cancer subtypes defined by joint hormone receptor and HER2 status. J Natl Cancer Inst. 2014;106(5).

[iv] CRUK About breast cancer staging and grades. https://www.cancerresearchuk.org/about-cancer/breast-cancer/stages-types-grades/about-breast-cancer-staging-grades. Accessed: September 16, 2020.

[v] Reinert T and Barrios CH. Optimal Management of Hormone Receptor Positive Metastatic Breast Cancer in 2016. Ther Adv Med Oncol. 2015;7(6):304-20.