QUALITY OF LIFE (QOL) RESULTS FROM THE PHASE 3 REVEL STUDY OF RAMUCIRUMAB + DOCETAXEL (RAM + DTX) VERSUS PLACEBO + DOCETAXEL (PL + DTX) IN ADVANCED/METASTATIC NSCLC PATIENTS (PTS) WITH PROGRESSION AFTER PLATINUM BASED CHEMOTHERAPY


1. Translational Research in Oncology-US Network, David Geffen School of Medicine at UCLA, Santa Monica, CA, USA
2. Medical Oncology, Institute of Oncology Ion Chiricuta and University of, Cluj-Napoca, ROMANIA
3. Thoracic Oncology Unit, Instituto Nacional de Cancerología, Mexico City, MEXICO
4. Medical Oncology, Tata Memorial Hospital, Mumbai, INDIA
5. Oncology Unit GPP, Athens School of Medicine, Athens, GREECE
6. Pulmonary Medicine, Ege University, School of Medicine, Izmir, TURKEY
7. Division of Hem/onc, Department of Medicine, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, KOREA
8. Oncology, Centro de Investigaciones Clinicas. Clinica Viedma S. A., Viedma, ARGENTINA
9. Chemotherapy, Wojewódzkie Centrum Onkologii, Gdask, POLAND
10. Oncology, Charing Cross Hospital, London, UK
11. Translational Lung Research Center Heidelberg, Internistische Onkolgie der Thoraxtumoren, Thoraxklinik im Universitätsklinikum Heidelberg, Translational Lung Research Center Heidelberg (TLRC-H), Heidelberg, GERMANY
12. Oncology, Cancer Center of Kansas, Wichita, KS, USA
13. Medical Oncology, Yonsei Cancer Center, Yonsei Univ. Health System, Seoul, KOREA
14. Thoracic Oncology, City Clinical Oncology Dispensary, St Petersburg, RUSSIAN FEDERATION
15. Medical Oncology, Eli Lilly and Co., Bridgewater, NJ, USA
16. Global Statistical Sciences, Eli Lilly and Company, Indianapolis, IN, USA
17. Medical Oncology, Eli Lilly and Company, Indianapolis, IN, USA
18. Thoracic Oncology, LungCanClinic Grosshansdorf, member of the German center for lung research (DLZ), Grosshansdorf, GERMANY
19. Oncology, Istituto Toscano Tumori, Livorno, ITALY

Aim: RAM + DTX significantly improved overall survival and progression-free survival in pts with locally advanced or metastatic NSCLC with progression after platinum based chemotherapy. Qol data was obtained.

Methods: Lung cancer symptom scale (LCSS) includes 6 symptom questions (loss of appetite, fatigue, cough, dyspnea, hemoptysis, pain) and 3 global items (symptom distress, difficulties with daily activities, global QoL) measured on a 0-100 mm scale, with higher scores representing greater symptom burden. LCSS and ECOG performance status (PS) data were collected at baseline (BL), every cycle, and at 30-day follow up (FU). LCSS total score and average symptom burden index (ASBI) were calculated. The primary prespecified analysis was time to deterioration (TtD) of the LCSS defined as increase from BL by ≥15 mm using the Kaplan-Meier method. TtD to PS ≥ 2 was also analysed.

Results: Of the 1253 pts randomized to receive RAM + DTX or PL + DTX, 66.6% were male, median age was 62, and 67.4% had PS1. Pt compliance with LCSS was approximately 75% and balanced across both arms. The mean BL LCSS total score was 27.3 (SD 17.08) and 29.6 (SD 17.59) on RAM + DTX and PL + DTX, respectively. During treatment, the symptom burden appeared similar between treatment arms. At 30-day FU, mean total LCSS score was 32.0 (SD 19.03) and 32.5 (SD 19.87) on RAM + DTX and PL + DTX, respectively, reflecting a similar increase in symptom burden for both arms (mean increase of 5.4 and 6.0 from BL, respectively). The TtD for all LCSS scores was similar between treatment arms. Stratified HRs (95% CI) for LCSS total score and ASBI were HR = 0.99 (0.81, 1.22), p = 0.932 and HR = 0.93 (0.75, 1.15), p = 0.514 with approximately 70% of pts censored. TtD to PS ≥ 2 was similar between treatment arms (HR = 1.03; [95% CI: 0.85, 1.26], p = 0.742) with approximately 70% of pts censored. TtD to PS ≥ 2 was also analysed.

Conclusions: In addition to the improvement of clinical outcomes demonstrated in REVEL, the primary Qol analyses suggest that there was no detriment in QoL and pt functioning by adding RAM to DTX second line chemotherapy.

Disclosure: K. Park: Advisor – AVeo, Astellas, Bi, Astra Zeneca, Clovis, Daiichi Sankyo, Eli Lilly, Roche, M. Thomas: I receive speakers and AD-Board Honoraria from Lilly Roche BMS AD-Board Honoraria from AstraZeneca Novartis Pierre Fabre; S. Yurasov: I am a full time employee of Eli Lilly & Co. the Sponsor of this clinical study; A. Zimmermann: I am an employee of Eli Lilly and do own stock in Lilly; G. Cuyun Carter: Employee and stockholder of Eli Lilly and Company; M. Reck: Member of Adboard (compensated): Hoffmann-La Roche, Lilly, BMS, Pfizer, Novartis, Boehringer-Ingelheim, AstraZeneca Honoraria for lectures: Hoffmann-La Roche Lilly, BMS, Pfizer, Novartis, Boehringer-Ingelheim, AstraZeneca; M. Perol: Advisory Board for Roche. All other authors have declared no conflicts of interest.