LBA4 Long-term follow-up in the KEYNOTE-010 study of pembrolizumab (pembro) for advanced NSCLC, including in patients (pts) who completed 2 years of pembro and pts who received a second course of pembro

R.S. Herbst[1], E.B. Garon[2], D-W. Kim[3], B. Chul Cho[4], J.L. Pérez Gracia[5], J-Y. Han[6], C. Dubos Arvis[7], M. Majem[8], M. Forster[9], I. Monnet[10], S. Novello[11], Z. Szalai[12], M.A. Gubens[13], W-C. Su[14], G.L. Ceresoli[15], A. Samkari[16], E. Jensen[16], G.M. Lubiniecki[16], P. Baas[17]

[1]Medical Oncology, Yale University School of Medicine Medical Oncology, New Haven, CT, USA, [2]David Geffen School of Medicine at the University of California, Los Angeles, CA, USA, [3]Seoul National, University Hospital, Seoul, Republic of Korea, [4]Yonsei Cancer Center, Yonsei University College of Medicine, Seoul, Republic of Korea, [5]Medical Oncology, Clinica Universidad de Navarra, Pamplona, Spain, [6]Medical Oncology, National Cancer Center, Goyang-si, Republic of Korea, [7]Oncology, Centre François Baclesse, Caen, France, [8]Medical Oncology, Hospital de la Santa Creu I Sant Pau, Barcelona, Spain, [9]Oncology, University College Hospital, London, UK, [10]Oncology, Centre Hospitalier Intercommunal Créteil, Créteil, France, [11]Department of Oncology, San Luigi Gonzaga Hospital, University of Torino, Orbassano, Italy, [12]Pulmonological Department, Petz Aladár Teaching County Hospital, Gyor, Hungary, [13]University of California, San Francisco, CA, USA, [14]Oncology, National Cheng Kung University Hospital, Tainan, Taiwan, [15]Pneumological and Urological Oncology, Cliniche Humanitas Gavazzeni, Bergamo, Italy, [16]Oncology, Merck & Co., Inc., Kenilworth, NJ, USA, [17]The Netherlands Cancer Institute, The Academic Medical Hospital Amsterdam, Amsterdam, Netherlands

Background: In the global, open-label, phase 2/3 study KEYNOTE-010, pembro 10 mg/kg or 2 mg/kg Q3W improved OS vs docetaxel in pts with previously treated advanced NSCLC with PD-L1 TPS ≥50% and ≥1% (coprimary analyses) at median follow-up of 13.1 mo. We present long-term results overall, in pts who completed 35 cycles (~2 y) of pembro, and in pts who received a second course of pembro.

Methods: Pts aged >18 y with previously treated advanced NSCLC with PD-L1 TPS ≥1% were randomized 1:1:1 to pembro 10 mg/kg or 2 mg/kg Q3W, or docetaxel 75 mg/m^2 Q3W. Pts received pembro for 35 cycles, until disease progression/intolerable toxicity. Response was assessed every 9 wk (RECIST 1.1 by independent central review), and survival every 2 mo posttreatment. There was no difference between pembro doses in the primary analysis, thus doses were pooled in this analysis.

Results: As of March 16, 2018, median (range) follow-up was 42.6 (35.2–53.2) mo overall (N = 1033). Pembro improved OS vs docetaxel in pts with PD-L1 TPS ≥50% (HR, 0.53; 95% CI, 0.42–0.66; P < 0.00001) and TPS ≥1% (HR, 0.69; 95% CI, 0.60–0.80; P < 0.00001). In pts with PD-L1 TPS ≥50%, median (95% CI) OS was 16.9 (12.3–21.4) mo with pembro vs 8.2 (6.4–9.8) mo with docetaxel; 36-mo OS rates were 35% vs 13%, respectively. Similar to the primary analysis, 16% of pembro pts and 36% of docetaxel pts had grade 3–5 treatment-related AEs. 79 of 690 pembro pts received 35 treatment cycles (~2 y). 36-mo OS rate among these 79 pts was 99% and 75 (95%) had PR/CR as best response; 72 pts (91%) remained alive. 48 pts (64%) had an ongoing response; median duration of response was not reached (range, 4–46+ mo). 25 of 79 pts (32%) had PD (investigator review) after stopping 35 cycles of pembro. 14 pts received second course pembro, 5 of whom completed 17 cycles; 6 (43%) had PR, 5 (36%) had SD, and 11 (79%) remained alive.

Conclusions: At 43-mo follow-up, pembro continued to prolong OS vs docetaxel in pts with previously treated, PD-L1–expressing advanced NSCLC, with manageable long-term safety. Most pts who completed 35 cycles (~2 y) of pembro had durable response. The majority of pts with PD by investigator review who received second course pembro had either PR or SD and remained alive.

Editorial acknowledgement: Medical writing and editorial assistance was provided by C4 MedSolutions, LLC (Yardley, PA), a CHC Group company. This assistance was funded by Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

Clinical trial identification: NCT01905657.

Legal entity responsible for the study: Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

Funding: Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

Disclosure: R.S. Herbst: Consulting role: Eli Lilly, Genentech/Roche, Merck, NextCure, Novartis, Pfizer; Research support: AstraZeneca, Eli Lilly, Merck. E.B. Garon: Funding to institution: Merck & Co., Inc., AstraZeneca, Eli Lilly, Genentech, Bristol-Myers Squibb, Pfizer, Novartis, Mirati. B. Chul Cho: Honoraria: AstraZeneca, Roche, Boehringer Ingelheim; Research funding: Bayer, AstraZeneca, Yuhan, Novartis; Consultant or advisor: AstraZeneca, Roche, Boehringer Ingelheim; Speakers' bureau: AstraZeneca, Bristol-Myers Squibb, Merck Sharp & Dohme, Novartis. J.L. Pérez Gracia: Grants: Merck Sharp & Dohme, Bristol-Myers Squibb, Roche, Lilly; Advisor, speakers' bureau: Bristol-Myers Squibb, Roche. J-Y. Han: Honoraria: AstraZeneca, Roche, Bristol-Myers Squibb, Merck Sharp & Dohme; Research funding: Roche;

Consultant or advisor: AstraZeneca, Bristol-Myers Squibb, Merck Sharp & Dohme, Novartis, Eli Lilly. M. Majem: Consultant or advisor: AstraZeneca, Roche, Boehringer Ingelheim, Bristol-Myers Squibb, Merck Sharp & Dohme, Novartis. M. Forster: Research grants: AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Merck Sharp & Dohme, Merck; Honoraria for advisory and consultancy roles: Achilles, AstraZeneca, Bristol-Myers Squibb, Celgene, Eli Lilly, Merck, Merck Sharp & Dohme, Novartis, Pfizer, PharmaMar, Roche. I. Monnet: Congress invitations: Roche, AstraZeneca. S. Novello: Funding to institution: Merck Sharp & Dohme; Speakers bureau: Eli Lilly, Takeda, Roche, AstraZeneca, Merck Sharp & Dohme, Boehringer Ingelheim. M.A. Gubens: Research grant to institution: Merck & Co., Inc.; Personal fees for consulting: AbbVie, Ariad, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Calithera, Clovis, Genentech-Roche, Mersana, Nektar, Novartis, Pfizer. A. Samkari, E. Jensen, G.M. Lubiniecki: Employee of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA. P. Baas: Consulting role: Genentech/Roche, Merck, Bristol-Myers Squibb, Pfizer; Research support: Bristol-Myers Squibb, Roche, Merck. All other authors have declared no conflicts of interest.