Randomized results of fixed-duration (1-yr) vs continuous nivolumab in patients (pts) with advanced non-small cell lung cancer (NSCLC)


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Background: Nivolumab, the anti-programmed death (PD)-1 antibody, has demonstrated durable responses and survival benefit in pts with advanced NSCLC, with some pts continuing to derive benefit even after discontinuation of nivolumab (due to adverse events [AEs] or a stopping rule). This raises the question of whether continuous nivolumab treatment is necessary for long-term benefit.

Methods: Pts with stage IIIB/IV NSCLC and ≥1 prior systemic therapy were enrolled and treated with nivolumab 3 mg/kg IV Q2W. The primary objective of the study overall was the incidence of high-grade (grade 3–5) select treatment-related AEs. Pts still on treatment at 1 yr were randomized 1:1 either to continue nivolumab until progressive disease, unacceptable toxicity, or withdrawal of consent (continuous-treatment arm), or to discontinue treatment, with the possibility of resuming treatment upon disease progression (fixed-duration arm).

Results: Of 319 pts enrolled and treated, 218 pts were randomized after 1 yr of treatment to the continuous-treatment arm (n = 111) or the fixed-duration arm (n = 107). Of these 218 pts, 133 (61%) had received ≥2 prior therapies and 10 (5%) had baseline ECOG PS ≥2. Data from an upcoming database lock (at which time, the expected post-randomization follow-up ≥10.7 mos) will be presented for randomized pts and will include overall survival, progression-free survival, and safety. In addition, data from pts who were re-treated in the fixed-duration arm will be presented.

Conclusions: The results from CheckMate 153 represent the first insights from a randomized trial evaluating the impact of stopping treatment with a PD-1/PD-L1 inhibitor at 1 yr vs continuing treatment in pts with advanced, previously treated NSCLC.

Clinical trial identification: NCT02066636

Legal entity responsible for the study: Bristol-Myers Squibb

Funding: Bristol-Myers Squibb

Disclosure: D.R. Spigel: Served as a consultant or advisor for Genentech/Roche (Inst), Novartis (Inst), Celgene (Inst), Bristol-Myers Squibb (Inst), Lilly (Inst), AstraZeneca (Inst), Pfizer (Inst), Clovis Oncology (Inst), Boehringer Ingelheim (Inst); travel funding from Genentech/Roche, Novartis, Celgene, Bristol-Myers Squibb, Lilly, AstraZeneca, Pfizer, Clovis Oncology, Biodexis, Boehringer Ingelheim, Peregrine Pharmaceuticals; owns stock in Foundation Medicine, Illumina; received institutional research funding from Genentech/Roche, Novartis, Celgene, Bristol-Myers Squibb, Lilly, AstraZeneca, Pfizer, Clovis Oncology, Boehringer Ingelheim, Peregrine Pharmaceuticals, Oncogenex, OncoMed Pharmaceuticals, Inc., Verastem, Daichi Sankyo, University of Southernwestern Medical Center – Simmons Cancer Center, Merck. D.M. Waterhouse: Served as consultant for BMS and Lilly; participated in speakers’ bureau for BMS, Celgene, Genentech/Roche, and Lilly. L. Einhorn: Served as a consultant for Celgene and ZIOPHARM Oncology; owns stock or other ownership interests with Amgen and Biongen Inc. L. Horn: Served as consultant for BMS, Merck, Buyer, Xcovery, GNE, BI, and Lilly; received honoraria for Biodexis; institution received research funding for AstraZeneca. B. Creelan: Participated on a speakers’ bureau for AstraZeneca and BMS; received research funding for Boehringer Ingelheim; travel funding from AstraZeneca, Merck Sharp & Dohme. S. Babus: Received research funding, consultancy fees, and travel honoraria from Alexion Pharmaceuticals. N.B. Leighl: Received honoraria from Pfizer; received institutional research funding from Novartis; travel funding from AstraZeneca and Merck, Sharp & Dohme. J. Chandler: Served as consultant for BMS; participated in speakers’ bureau for Janssen; received research funding from BMS, EMD Serono, GNE/Roche, GSK, Lilly, and Onyx; travel funding from BMS and Janssens. G. Goss: Received honoraria from AZ, BI, BMS, Lilly, Pfizer; served as a consultant or advisor for AZ, BI, BMS; and received travel funding from AZ, BI, BMS, Pfizer. E.B. Garon: Institution received research funding from Merck, Genentech, AstraZeneca, Novartis, Pfizer, Lilly, Bristol-Myers Squibb, and Boehringer Ingelheim. A. Li, N. Aanur: Employed by BMS and owns stock in BMS. R. Jotte: Received honoraria from Bristol-Myers Squibb and Lilly; participated in speakers’ bureau for Bristol-Myers Squibb and Lilly. All other authors have declared no conflicts of interest.