Neoadjuvant nivolumab + chemotherapy in resectable non-small cell lung cancer (CheckMate 816)

Jonathan Spicer,1 Changhi Wang,2 Fumihiro Tanaka,3 Gene B. Saylor,4 Ke-Neng Chen,5 Moishe Liberman,6 Everett Vokes,7 Nicolas Girard,4 Shun Lu,5 Mariano Provenzol,6,7 Tetsuya Mitsudomi,8,9 Mark A. Awad,10 Enriqueta Felip,11 Patrick M. Forde,12 Scott J. Swanson,12 Julie R. Brahmer,12 Keith Kerr,13 Cécile Dorange,14 Junliang Cai,15 Stephen Broderick16

Neujoma Oncology Center Health Center, Montreal, QC, Canada; 1Jinan Lung Cancer Institute, Tianjin University Cancer Institute and Hospital, Tianjin, China; 2University of Occupational and Environmental Health, Kitakyushu, Japan; 3Charleston Oncology, Charleston, SC, USA; 4Peking University School of Oncology, Beijing Cancer Hospital, Beijing, China; 5Centre hospitalier de l’Université de Montréal, Montréal, QC, Canada; 6University of Chicago Medicine, Chicago, IL, USA; 7Institut du thorax Curie-Montsouris, Institut Curie, Paris, France; 8Shanghai Lung Cancer Center, Shanghai Chest Hospital, Shanghai Jiaotong University, Shanghai, China; 9Kindai University Faculty of Medicine, Ohno-Higashi, Osaka-Sayama, Japan; 10Bard-Cancer Institute, Boston, MA, USA; 11 Vall d’Hebron University Hospital, Vall de Hebron University Institute of Oncology, Barcelona, Spain; 12 Johns Hopkins Kimmel Cancer Center, Baltimore, MD, USA; 13Abderriy Royal Infirmary, Aberdeen, UK; 14Bristol Myers Squibb, Princeton, NJ, USA

Introduction

Single-arm phase 2 trials with neoadjuvant immunotherapy-based regimens have shown encouraging efficacy outcomes (pathological complete response [pCR]; event-free survival [EFS], and overall survival [OS]) without compromising the feasibility of surgery for patients with resectable non-small cell lung cancer (NSCLC).

In the neoadjuvant phase 1 CheckMate 816 study (NCT02887577), neoadjuvant nivolumab (NIVO) + chemotherapy (chemo) showed significant improvement in pCR in a primary endpoint in patients with resectable NSCLC, while maintaining a favorable safety profile.

• pCR rate was 24% vs 2% in the intent-to-treat (ITT) population; odds ratio (OR), 13.94 (95% CI, 2.57–75.34); P < 0.0001

• Major pathological response (MPR) rate was 36% vs 8% in the ITT population; odds ratio (OR), 5.62 (95% CI, 1.46–21.26)

• Here, we present efficacy data as well as key surgical outcomes in all randomized patients at change of status.