

Monday, April 16, 2018

Alice T. Shaw, MD, PhD, co-chair of the AACR Annual Meeting Clinical Trials Committee and director of the Center for Thoracic Cancers at Massachusetts General Hospital Cancer Center, will moderate a press conference highlighting the following research:

- [KEYNOTE-189 Met its Dual Primary Endpoints of Overall Survival and Progression-free Survival](#)
 - Will be simultaneously published in *The New England Journal of Medicine*.
- [CheckMate -227 Met its Co-primary Endpoint of Progression-free Survival](#)
 - Will be simultaneously published in *The New England Journal of Medicine*.
- [Neoadjuvant Nivolumab was Safe, Yielded Pathologic Responses in Patients With Resectable Lung Cancer](#)
 - Will be simultaneously published in *The New England Journal of Medicine*.
- [An Off-the-shelf, Dual-targeted CAR T-cell Product Showed Promising Results in Preclinical Studies](#)

KEYNOTE-189 Met its Dual Primary Endpoints of Overall Survival and Progression-free Survival

CHICAGO—Patients with newly diagnosed metastatic non squamous non-small cell lung cancer (NSCLC) who received pembrolizumab (Keytruda) plus chemotherapy had significantly longer overall survival (OS) and progression-free survival (PFS) compared with those who received chemotherapy alone, according to data from the phase III clinical trial KEYNOTE-189, presented at the AACR Annual Meeting 2018, April 14-18.

This study is being simultaneously published in *The New England Journal of Medicine* (see bottom of page).

“The long-term survival of patients with advanced NSCLC remains poor and the standard of care for most

patients is chemotherapy, which affords a survival benefit measured in months,” said Leena Gandhi, MD, PhD, associate professor in the Department of Medicine and director of Thoracic Medical Oncology Program, Perlmutter Cancer Center at NYU Langone Health.

In May 2017, the U.S. Food and Drug Administration approved pembrolizumab plus pemetrexed and carboplatin-based chemotherapy as first-line treatment for patients with advanced nonsquamous NSCLC based on data from the phase II cohort G of the KEYNOTE-021 study, but it was not widely adopted in the absence of positive results from a phase III study, Gandhi explained. “Further, the phase II study did not initially demonstrate a survival benefit,” she said.

“Results from KEYNOTE-189 are practice-changing,” noted Gandhi. “This phase III trial demonstrated an improvement in overall response rate (ORR), PFS, and OS across all groups of patients, irrespective of PD-L1 expression, halving the risk of death, which is an unprecedented effect of therapy in the first-line setting for advanced nonsquamous NSCLC without EGFR or ALK alterations.”

KEYNOTE-189 is a randomized, double-blind, phase III study in patients with metastatic nonsquamous NSCLC who received no prior treatment for metastatic disease. Patients (616) were randomized, 2:1, to receive pemetrexed and a platinum-based chemotherapy plus either pembrolizumab (test arm) or placebo (control arm). Patients were stratified based on PD-L1 tumor proportion score (