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Efficacy of Nivolumab is Enhanced in Small Cell Lung Cancer Patients with High Tumor Mutation Burden with or without Ipilimumab

Yokohama, Japan – October 16, 2017 – New research uncovered that among small cell lung cancer (SCLC) patients, the efficacy of using nivolumab with or without (\pm) ipilimumab was enhanced among those with a high tumor mutation burden (TMB). Dr. Naiyer Rizvi of Columbia University Medical Center in the United States presented these findings today at the International Association for the Study of Lung Cancer (IASLC) 18th World Conference on Lung Cancer (WCLC) in Yokohama, Japan.

Initial findings from CheckMate 032, a phase 1/2 clinical trial evaluating nivolumab \pm ipilimumab in solid tumors, showed that this treatment is promising. However, there have been no clear biomarkers to predict patient response. The researchers chose to use an exploratory analysis of CheckMate 032 to search for improved biomarkers in SCLC. CheckMate 032 evaluated treatment with nivolumab \pm ipilimumab in both non-randomized and randomized cohorts, which the researchers pooled for the analysis. Additionally, they conducted whole exome sequencing (WES) on tumors and matched blood samples and equally divided patients into low, medium and high TMB cohorts.

The researchers found that among the patients with an evaluable TMB result who were treated with only nivolumab, objective response rate (ORR), progression-free survival (PFS) and overall survival (OS) were improved in the high TMB cohort as compared to the medium and low TMB cohorts. Enhanced benefits in the high TMB cohort were seen most dramatically among those treated with nivolumab and ipilimumab – the response rate was 46.2% and 1 year overall survival was 62.4%. Additionally, the researchers found that in each cohort of TMB, nivolumab plus ipilimumab outperformed nivolumab treatment alone.

Their findings highlight that high TMB is associated with improved responses to nivolumab \pm ipilimumab in patients with SCLC and suggest that TMB may be a relevant biomarker across all patients with lung cancers.

“The results from our study provide the clearest evidence to date demonstrating the power of TMB as a biomarker,” said Dr. Rizvi. “This may even begin to impact prescribing practice in SCLC by clarifying the benefit that can be achieved for some patients, encouraging molecular testing for estimating mutation burden in SCLC and using greater precision to identify subgroups of patients with SCLC who may exceptionally benefit from nivolumab with ipilimumab.”

About the WCLC

The World Conference on Lung Cancer (WCLC) is the world's largest meeting dedicated to lung cancer and other thoracic malignancies, attracting over 6,000 researchers, physicians and specialists from more than 100 countries. The goal is to disseminate the latest scientific achievements; increase awareness, collaboration and understanding of lung cancer; and to help participants implement the latest developments across the globe. Organized under the theme of "Synergy to Conquer Lung Cancer," the conference will cover a wide range of disciplines and unveil several research studies and clinical trial results. For more information, visit <http://wclc2017.iaslc.org/>.

About the IASLC

The International Association for the Study of Lung Cancer (IASLC) is the only global organization dedicated to the study of lung cancer and other thoracic malignancies. Founded in 1974, the association's membership includes more than 6,500 lung cancer specialists across all disciplines in over 100 countries, forming a global network working together to conquer lung and thoracic cancers worldwide. The association also publishes the Journal of Thoracic Oncology, the primary educational and informational publication for topics relevant to the prevention, detection, diagnosis and treatment of all thoracic malignancies. Visit www.iaslc.org for more information.

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