

Addition of sintilimab to pemetrexed and platinum improved progression-free survival

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The interim analysis of ORIENT-11, a phase III double-blind randomized trial has shown a nearly two-fold increase in progression-free survival with addition of sintilimab to chemotherapy in patients with advanced or metastatic non-squamous non-small cell lung cancer without EGFR or ALK genomic aberrations, according to research data presented today at the International Association for the Study of Lung Cancer Virtual Presidential Symposium.

The research findings are also published simultaneously in the *Journal of Thoracic Oncology*, the journal of the International Association for the Study of Lung Cancer.

Previously, sintilimab in combination with pemetrexed and a platinum-based chemotherapy had shown promising activity for nonsquamous non small cell [lung cancer](#) in a phase 1b study, according to Li Zhang, M.D., of Sun Yat-sen University Cancer Center, Guangzhou, China.

Dr. Zhang and investigators from centers in China enrolled 397 patients in the study. Of these, 266 and 131 patients were randomly assigned to the sintilimab combination and to placebo combination, respectively. Patients with all ranges of PD-L1 expression (by tumor proportion score, TPS) were included. The median progression free survival per was significantly improved in sintilimab-combination group compared to placebo combination group (8.9 vs. 5.0 months)

Dr. Zhang reported that sintilimab-combination group showed a

nominally significant improvement of overall survival. The overall response rate also was improved for the sintilimab-combination group (51.9% versus 29%). The safety signal for the sintilimab combination was similar to that found in other studies, but rates of occurrence of grade > 3 adverse events were slightly higher in the sintilimab-combination group (61.7% versus 58.8%).

"This study demonstrated that the addition of sintilimab to chemotherapy significantly improved [progression-free survival](#) and a nominally improved overall survival, with an acceptable safety profile in [patients with] first-line non-squamous non [small cell lung cancer](#)," said Dr. Zhang. "In this study, we collected tumor samples at baseline of treatment. So, our next work will focus on biomarker exploration. By RNA sequencing of tumor samples, we look forward to searching a potential biomarker which can predict the survival benefit from PD-1 [combination](#) with chemotherapy."

Provided by International Association for the Study of Lung Cancer

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