



Chris Martin
CMartin@DavidJamesGroup.com | 630-670-2745

Becky Bunn, MSc
Becky.Bunn@IASLC.org | 720-325-2946

Embargoed for Tuesday, September 10 at 10:45 a.m. Barcelona Time

Patients Taking Nivolumab Experience Five-Fold Increase in Overall Survival Compared to Chemotherapy

Five-Year Outcomes from the Randomized, Phase 3 Trials CheckMate 017/057: Nivolumab vs Docetaxel in Previously Treated NSCLC

Barcelona— Pooled data on two clinical trials demonstrate patients taking nivolumab realized a greater than five-fold increase in five-year overall survival rate compared with the chemotherapy docetaxel. The presentation was made today by Dr. Scott Gettinger of Yale Comprehensive Cancer Center, New Haven, Conn., at the **IASLC 2019 World Conference on Lung Cancer**, hosted by the International Association for the Study of Lung Cancer.

Historically, outcomes for advanced non-small cell lung cancer have been poor, with five-year survival rates less than five percent with conventional chemotherapy. Nivolumab, a programmed death-1 inhibitor, was approved in 2015 for patients with previously treated advanced NSCLC based on two randomized phase three trials, CheckMate 017 and CheckMate 057, which demonstrated improved overall survival compared to docetaxel.

In CheckMate 017 and 057, 854 patients with advanced NSCLC, ECOG performance status 0 to 1, and progression during or after first-line platinum-based chemotherapy, were randomized 1:1 to nivolumab or docetaxel until progression or unacceptable toxicity. After completion of the primary analyses, patients in the docetaxel arm no longer receiving benefit could cross over to receive nivolumab. The researchers set overall survival as the primary endpoint for both studies.

At five-year follow-up, 50 nivolumab patients and nine docetaxel patients were alive. Baseline characteristics of five-year survivors in both arms were similar to the overall population and patients who survived less than one year, except for a higher percentage of patients with ECOG PS 0 or tumor programmed death ligand-1 (PD-L1) expression greater than one percent on nivolumab and ECOG PS 0 and Stage IIIB NSCLC on docetaxel. Nivolumab continued to show long-term overall survival and progression-free survival benefit compared to docetaxel with five-year survival rates of 13.4 percent vs 2.6 percent and progression-free survival rates 8.0 percent compared to 0 percent. The overall survival benefit with nivolumab compared with docetaxel was observed across subgroups, including patients with tumor PD-L1 expression <1 percent. No new safety signals were observed with longer follow-up. Between three- and five-year's follow-up, eight of the 31 (26 percent) nivolumab-treated patients reported a treatment-related adverse event, one (3 percent) grade three-four. The most common select adverse events (events with a potential immunological cause) were related to skin, in 4 (13 percent) patients, none of which were grade three or four.

“CheckMate 017 and 057 are the first phase three trials to report five-year outcomes for a PD-1 inhibitor in previously treated advanced NSCLC, demonstrating a greater than five-fold increase in five-year OS rates with nivolumab (13.4 percent) compared with docetaxel (2.6 percent). Nivolumab remained well tolerated with no new safety signals,” according to Dr. Gettinger.

About the WCLC:

The WCLC is the world’s largest meeting dedicated to lung cancer and other thoracic malignancies, attracting more than 7,000 researchers, physicians and specialists from more than 100 countries. The goal is to increase awareness, collaboration and understanding of lung cancer, and to help participants implement the latest developments across the globe. The conference will cover a wide range of disciplines and unveil several research studies and clinical trial results. For more information, visit wclc2019.iaslc.org.

About the IASLC:

The International Association for the Study of Lung Cancer (IASLC) is the only global organization dedicated solely to the study of lung cancer and other thoracic malignancies. Founded in 1974, the association's membership includes more than 7,500 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.

###