WCLC 2018: Nintedanib Plus Pemetrexed/Cisplatin Does Not Improve PFS or OS in Malignant Pleural Mesothelioma of Epithelioid Subtype

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Key Points

- The results of the study did not show any statistically significant and clinically meaningful improvements in the primary endpoint—PFS—or key secondary points.
- These results, which differed from the previously published phase II data, do not support the use of nintedanib in combination with pemetrexed/cisplatin for patients with malignant pleural mesothelioma of epithelioid subtype.

Findings from a recent study demonstrate that the triple angiokinase inhibitor nintedanib combined with standard-of-care pemetrexed (Alimta)/cisplatin does not impact progression-free survival (PFS) and overall survival (OS) for patients with unresectable malignant pleural mesothelioma with epithelioid histology. **Giorgio V. Scagliotti, MD, PhD**, of the University of Turin's Department of Oncology and S. Luigi Hospital and President of the International Association for the Study of Lung Cancer (IASLC), presented these findings at the IASLC 19th World Conference on Lung Cancer (Abstract PL02.09).

Phase III of the LUME-Meso Trial

Malignant pleural mesothelioma is a rare but aggressive disease and, if left untreated, median survival is 6 to 9 months. Standard first-line treatment of pemetrexed/cisplatin typically yields a median OS of approximately 1 year for patients with unresectable malignant pleural mesothelioma. When phase II data of the LUME-Meso trial showed patients with epithelioid histology derived the greatest benefit from nintedanib added to pemetrexed/cisplatin in terms of improved PFS vs placebo and a trend towards improved OS, the phase III protocol of LUME-Meso was amended to focus solely on this subgroup.

Phase III of the global, randomized, double-blind, placebo-controlled study evaluated 458 patients with confirmed malignant pleural mesothelioma of

epithelioid subtype with no previous systemic chemotherapy and an Eastern Cooperative Oncology Group performance status between 0 and 1. Patients were randomized 1:1 to receive combination treatment with up to six cycles of pemetrexed (500 mg/m^2)/cisplatin (75 mg/m^2) on day 1, plus nintedanib (200 mg twice a day) or matched placebo on day 2 through day 21. After completing the combination treatment phase, patients with no disease progression received continued maintenance therapy with nintedanib or placebo.

Results

The results of the study did not show any statistically significant and clinically meaningful improvements in the primary endpoint—PFS—or key secondary points. These results, which differed from the previously published phase II data, do not support the use of nintedanib in combination with pemetrexed/cisplatin for patients with malignant pleural mesothelioma of epithelioid subtype.

“Unfortunately, thephase III results of LUME-Meso did not confirm that nintedanib in combination with pemetrexed/cisplatin prolongs patients’ lives,” said Dr. Scagliotti. “However, the trial reaffirms the need for solid confirmatory studies that are adequately sized to challenge the standard of care in advanced malignant mesothelioma.”

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