
POSTER SESSION 2
SATURDAY, AUGUST 27, 2016

P2.01

LUME-MeSO: Phase II/III Study of Nintedanib + Pemetrexed/Cisplatin in Patients With Malignant Pleural Mesothelioma*Track: SCLC, Mesothelioma, Thymoma***Giorgio V. Scagliotti,¹ Rabab Gaafar,² Anna Nowak,³ Nicholas J. Vogelzang,⁴ Ute Von Wangenheim,⁵ Nassim Morsli,⁶ Derek Velema,⁷ Sanjay Popat⁸**

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Background: Median overall survival (OS) is ~1 year with pemetrexed/cisplatin, the standard front-line treatment for patients with unresectable malignant pleural mesothelioma (MPM); additional improvements in therapy are needed. Nintedanib is an oral, twice-daily (bid), triple angiokinase inhibitor of vascular endothelial growth factor (VEGF) receptors 1–3, platelet-derived growth factor receptors α/β , and fibroblast growth factor receptors 1–3, as well as Src and Abl kinases, which are involved in regulating tumor angiogenesis, growth, and metastasis of MPM. Inhibition of the VEGF pathway has been validated as a treatment approach for MPM with bevacizumab (Zalcman G, et al. *Lancet* 2016;387:1405–14). Nintedanib (Ofev[®]) monotherapy is approved in the USA and EU for idiopathic pulmonary fibrosis. Nintedanib (VARGATEF[®]) in combination with docetaxel is approved in the European Union and other countries for locally advanced, metastatic or locally recurrent non-small cell lung cancer of adenocarcinoma histology after first-line chemotherapy and has shown clinical benefit in trials in several tumor types. LUME-Meso is an international, double-blind, randomized,

multicenter, placebo-controlled Phase II/III study, evaluating the efficacy and safety of nintedanib combined with pemetrexed/cisplatin for the treatment of unresectable MPM. Following a data review by the internal Data Monitoring Committee (DMC) after all planned Phase II patients had been enrolled, the Phase II exploratory study was extended to a confirmatory Phase II/III trial. The trial is ongoing.

Method: Chemo-naïve patients from 27 countries (≥ 18 years of age, Eastern Cooperative Oncology Group Performance Status 0–1, and histologically confirmed epithelioid/biphasic MPM; 87 pts in Phase II/450 pts in Phase III) will be randomized (1:1) to receive up to 6 cycles of pemetrexed (500 mg/m²)/cisplatin (75 mg/m²) on Day 1 plus nintedanib (200 mg bid) or placebo on Days 2–21. Patients without disease progression (PD) will continue to receive maintenance treatment with nintedanib monotherapy/placebo until PD. The primary endpoint is progression-free survival (PFS); OS is the key secondary endpoint. The study will use an adaptive design strategy, with sample size reassessment by an external DMC based on interim analysis to ensure sufficient power for PFS/OS. Additional secondary endpoints include objective tumor response and disease control according to modified Response Evaluation Criteria in Solid Tumors. Other assessments include frequency/severity of adverse events, laboratory parameters, change in forced vital capacity (Phase II only), health-related quality of life and exploratory predictive biomarker analyses in tumor/blood specimens.

Results: Not applicable.

Conclusion: The study is currently enrolling patients into Phase III and will help to determine the efficacy and safety of nintedanib in patients with unresectable MPM. Clinical trial identifier: **NCT01907100**.

Keywords: Mesothelioma, Nintedanib, Angiogenesis, Clinical trial

P2.02**Thymic Malignancies. A Single Institution Series From 2006-2016***Track: SCLC, Mesothelioma, Thymoma***Flavio L. Cabral,¹ Maria Teresa Ruiz Tsukazan,² Jayme O. Rios,¹ Jayme R. Heck,¹ Gabriel M. Schwarcke,¹ Renata M. Rosenthal,¹ Maicon J. Cimarosti,¹ João R. Schmitt,¹**