LUME-MESO TRIAL: PHASE II RESULTS[1]

ENCOURAGING PHASE II SURVIVAL DATA FOR ORAL NINTEDANIB IN MALIGNANT PLEURAL MESOTHELIOMA

LUME-Meso is a phase II/III randomised, double-blind trial designed to assess efficacy and safety of nintedanib plus chemotherapy as a first-line treatment for unresectable (unable to be removed with surgery) malignant pleural mesothelioma (MPM)

TRIAL DESIGN

INCLUSION CRITERIA

- Have not previously had chemotherapy
- Have unresectable non-sarcomatoid MPM
- Male or female ≥18 years of age
- Epithelioid and biphasic histology
- ECOG performance status 0–1
- Life expectancy of at least 3 months
- Measurable disease according to mRECIST criteria

87 PATIENTS RANDOMISED 1:1

Stratified by epithelioid or biphasic

44 patients → Nintedanib 200 mg bid + pemetrexed /cisplatin

43 patients → Placebo 200 mg bid + pemetrexed /cisplatin

Primary endpoint: **Progression-free Survival (PFS)**

Secondary endpoints: **Overall survival (OS) and objective tumour response**

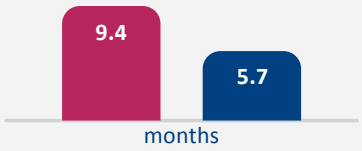
RESULTS

nintedanib placebo

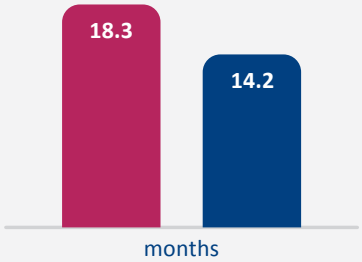
Total Population

The addition of nintedanib in combination with chemotherapy DEMONSTRATED IMPROVED CLINICAL EFFICACY

Median PFS improved by **3.7 months** (HR=0.54; P=.010)



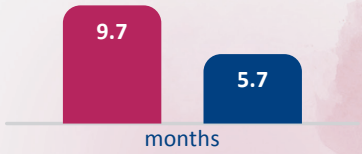
Median OS gain of **4.1 months** (HR = 0.77; P=.319)



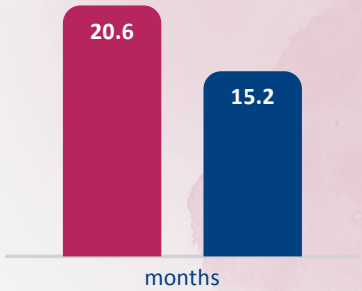
Epithelioid Subset

The greatest improvement was observed in PATIENTS WITH EPITHELIOID HISTOLOGY

Median PFS by **4.0 months** (HR=0.49; P=.006)



Median OS gain of **5.4 months** (HR=0.70; P=.197)



SAFETY PROFILE

The overall safety profile of nintedanib in combination with chemotherapy was as expected. Adverse Events (AEs) were manageable with no new safety signals.

- The most frequently reported AEs (≥60% of patients, any CTCAE grade) in the nintedanib arm and more frequent with nintedanib than placebo were diarrhea and neutropenia
- Incidence of adverse events commonly associated with antiangiogenic agents were either balanced between treatment arms or reported in lower numbers of patients in the nintedanib arm

CONCLUSION

The addition of nintedanib to standard chemotherapy regimens demonstrated an improved clinical efficacy in the first-line treatment of patients with malignant pleural mesothelioma. Shown by:

- **Improvements in progression-free survival**
- **A trend towards improved overall survival**

LUME-Meso

1. Nowak A. et al. Mature overall survival (OS) results from the LUME-Meso study of nintedanib (N) + pemetrexed/cisplatin (PEM/CIS) vs placebo (P) + PEM/CIS in chemo-naïve patients (pts) with malignant pleural mesothelioma (MPM). (Abstract #8506) at American Society of Clinical Oncology, Chicago, June 5, 2017