LUME-Meso: Phase III study of nintedanib + pemetrexed/cisplatin in patients with malignant pleural mesothelioma

A double-blind, randomised, global, multicentre, Phase III study of nintedanib in combination with pemetrexed/cisplatin, followed by continuing nintedanib monotherapy versus placebo in combination with pemetrexed/cisplatin, followed by continuing placebo monotherapy for the treatment of patients with unresectable malignant pleural mesothelioma.

Endpoints

- **Primary endpoint:** PFS
- **Secondary endpoints:** OS (key), objective tumour response evaluated according to mRECIST, disease control according to mRECIST
- **Selected additional endpoints:** best overall response according to mRECIST, percentage change from baseline in FVC and health-related quality of life

For more information about the LUME-Meso clinical trial (NCT01907100):

- **TALK:** with your local medical representative
- **VISIT:** www.LUMEMesoTrial.com
- **CALL:** Boehringer Ingelheim Call Center at 1-800-243-0127 (Toll-free within the United States)
- **EMAIL:** MEDLUMEMesoTrial.ING@boehringer-ingelheim.com

BID=twice daily; FVC=forced vital capacity; OS=overall survival; PD=progressive disease; PFS=progression-free survival.

*On Days 2 to 21.

*Pemetrexed 500 mg/m² IV over 10 minutes on Day 1 of each 21-day cycle; cisplatin 75 mg/m² IV over 2 hours on Day 1 of each 21-day cycle.

*Treatment beyond progression is allowed if clinical benefit is perceived.
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Study trial countries

Main inclusion criteria

- Male or female ≥18 years of age
- Histologically confirmed epithelioid malignant pleural mesothelioma
- ECOG PS 0 or 1
- Measurable disease according to mRECIST criteria

Main exclusion criteria

- Previous systemic chemotherapy for malignant pleural mesothelioma
- Prior treatment with nintedanib or any other systemic therapy
- Patients with sarcomatoid and biphasic subtype malignant pleural mesothelioma
- Patients with symptomatic neuropathy
- Radiotherapy within 3 months prior to baseline imaging
- Patients who may be eligible to undergo surgical resection
- Active brain metastases
- Patients with mild-to-moderate renal insufficiency taking NSAIDs and unable/unwilling to interrupt treatment

ECOG PS=Eastern Cooperative Oncology Group performance status; IV=intravenous; NSAID=non-steroidal anti-inflammatory drug.

Nintedanib is being investigated in malignant pleural mesothelioma and is not approved. Nintedanib efficacy and safety in malignant pleural mesothelioma have to be fully established.