Protocol : NINTEDANIB BI 1199.93

Double Blind, Randomised, Multicentre, Phase II/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.

This is the trial summary as assessed on clinicaltrials.gov on 30/06/2016.

Minor changes in the protocol may occur. You can check this on this direct link:

https://clinicaltrials.gov/ct2/results?term=1199.93&Search=Search

Trial Design :

This is a phase II/III confirmatory study designed to evaluate the safety and efficacy of nintedanib (BIBF 1120) in combination + (pemetrexed / cisplatin) followed by nintedanib (BIBF 1120) versus placebo + pemetrexed / cisplatin followed by placebo for the treatment of patients with unresectable malignant pleural mesothelioma.

Inclusion Criteria:

Histologically confirmed malignant pleural mesothelioma (MPM) (subtype: epithelioid or biphasic)

Life expectancy of at least 3 months in the opinion of the investigator

Eastern Cooperative Oncology Group (ECOG) score of 0 or 1

Measurable disease according to modified RECIST (Response Evaluation Criteria In Solid Tumours) criteria

Exclusion Criteria:

Previous systemic chemotherapy for MPM

Prior treatment with nintedanib or any other prior line of therapy

Patients with sarcomatoid subtype MPM

Patients with symptomatic neuropathy

Radiotherapy (except extremities) within 3 months prior to baseline imaging

Active brain metastases (e.g. stable for < 4 weeks)

Radiographic evidence of cavitary or necrotic tumours or local invasion of major blood vessels by MPM

Significant cardiovascular diseases

Inadequate hematologic, renal, or hepatic function