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LUME-COLON 1

A double-blind, randomised, placebo controlled phase III study of nintedanib* plus best supportive care (BSC) versus placebo plus BSC in patients with metastatic colorectal cancer (mCRC) who no longer responded to, or tolerated, other available treatments[1]

Trial design

LUME-Colon 1 evaluated the efficacy and safety of nintedanib in patients with mCRC after failure of previous treatment with standard chemotherapy and biological agents

Patients with mCRC who no longer responded to, or tolerated, other available treatments → RANDOMISED

- Nintedanib plus BSC (200mg bid) 386 patients
- Placebo plus BSC (200mg bid) 382 patients

CO-PRIMARY ENDPOINTS:

- Progression-Free Survival (PFS: length of time before the tumour starts to progress after randomisation)
- Overall survival (OS: length of time a patient has survived after randomisation)

SECONDARY ENDPOINTS INCLUDED:

- Objective tumour response and disease control

Inclusion criteria[1]

- Metastatic or locally advanced colorectal cancer who no longer responded to, or tolerated, other available treatments
- Eastern Cooperative Oncology Group (ECOG) performance status ≤1
- Age ≥18 years
- At least one measurable lesion according to Response Evaluation Criteria In Solid Tumours (RECIST) version 1.1

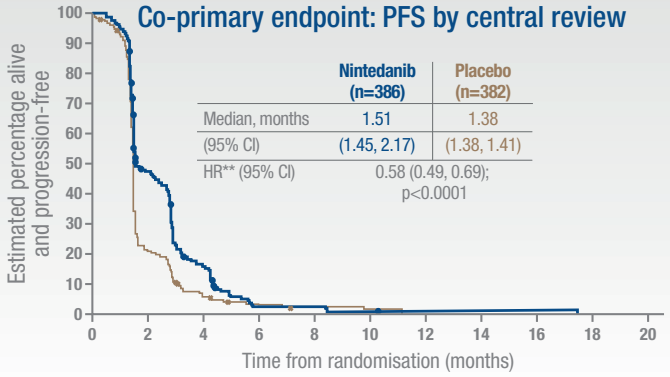
Participants

- LUME-Colon 1 was conducted at 150 sites worldwide
- 764 patients were randomised

What did the results show?[1]

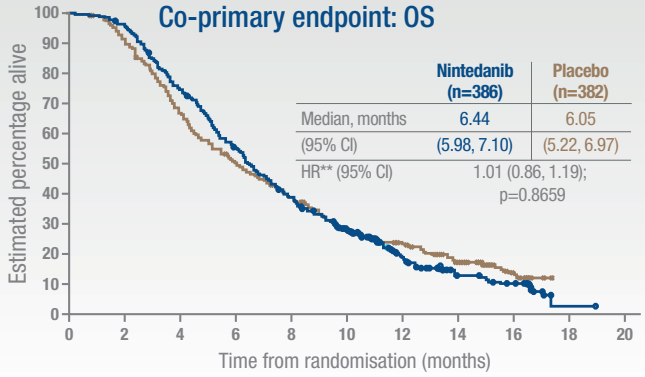
Nintedanib Placebo

Co-primary endpoint: PFS by central review



	Nintedanib (n=386)	Placebo (n=382)
Median, months	1.51	1.38
(95% CI)	(1.45, 2.17)	(1.38, 1.41)
HR** (95% CI)	0.58 (0.49, 0.69); p<0.0001	

Co-primary endpoint: OS



	Nintedanib (n=386)	Placebo (n=382)
Median, months	6.44	6.05
(95% CI)	(5.98, 7.10)	(5.22, 6.97)
HR** (95% CI)	1.01 (0.86, 1.19); p=0.8659	

Nintedanib demonstrated clear anti-tumour activity and significantly reduced the risk of disease progression by 42%. However, improvement in PFS did not translate to an improvement in OS

Safety profile[1]

- Nintedanib was well-tolerated and the data showed that the adverse events were consistent with those observed in previous oncology trials, with no new or unexpected safety signals
- The most frequent ≥Grade 3 adverse events were liver related investigations (16% nintedanib vs 8% placebo and fatigue (9% nintedanib vs 6% placebo)

*Nintedanib is approved in the EU under the brand name Vargatef® for use in combination with docetaxel in adult patients with locally advanced, metastatic or locally recurrent NSCLC of adenocarcinoma tumour histology after first-line chemotherapy. Nintedanib is under regulatory review by health authorities in other countries outside the EU. Nintedanib is not approved in other oncology indications.

**Stratified by previous treatment with regorafenib, time from onset of metastatic disease until randomisation, and region.

1. Van Cutsem E, *et al.* Nintedanib plus best supportive care (BSC) versus placebo plus BSC for the treatment of patients (pts) with metastatic colorectal cancer (mCRC) refractory to standard therapies: results of the Phase III LUME-Colon 1 study. Abstract #LBA20_PR presented at the European Society of Medical Oncology (ESMO) 2016 Congress in Copenhagen, Denmark, 7 – 11 October. ClinicalTrials.gov Identifier: NCT02149108 https://clinicaltrials.gov/ct2/show/NCT02149108?term=LUME+colon+1&rank=1

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