gastrointestinal tumours, colorectal

**LUME-COLON 1: DOUBLE-BLIND, RANDOMISED PHASE III STUDY OF NINTEDANIB (BIBF 1120) PLUS BEST SUPPORTIVE CARE (BSC) VERSUS PLACEBO PLUS BSC IN PATIENTS (PTS) WITH REFRACTORY COLORECTAL CANCER**


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**Background:** Clinical studies with anti-VEGF agents demonstrate that angiogenesis is critical to colorectal (CRC) tumour growth and metastasis. Nintedanib (N) is a triple angiokinase inhibitor of VEGF, PDGF and FGF signalling. Phase II studies showed that 1st-line N monotherapy has similar efficacy to 1st-line sunitinib or sorafenib in VEGF-sensitive cancers like renal cell carcinoma (NCT01024920; 1199.26) and hepatocellular cancer (NCT01004003; 1199.37), respectively. N has also shown clinical activity and a manageable safety profile in phase III trials with NSCLC (NCT00805194; 1199.13 and NCT00806819; 1199.14) and ovarian cancer (NCT01015118, 1199.15). These findings provide a rationale to examine N in refractory CRC. The objective of this study is to evaluate PFS, OS and safety of N in pts with metastatic CRC after failure with standard chemotherapy and biological agents.

**Trial design:** 764 pts from approximately 150 sites worldwide—at least 18 years of age, ECOG score 0–1, and histologically/cytologically confirmed CRC adenocarcinoma not amenable to surgery and/or radiotherapy—will be randomised 1:1 to receive either N (200 mg bid) + BSC or placebo (bid) + BSC in 21-day courses until disease progression or undue toxicity. The study is adequately designed and powered for distinguishing a clinically meaningful effect in the primary endpoint PFS and the key secondary endpoint OS. Other secondary endpoints are objective tumour response and disease control. Pts will be stratified at randomisation based on previous regorafenib treatment (yes vs no), time from onset of metastatic disease until randomisation in the trial (<24 months vs ≥24 months) and region (ie, Western Europe, North America and Australia; Asia; and rest of the world). PFS and OS will be evaluated by the log rank test to determine the effect of N hierarchically at the two-sided alpha level of 0.05. Other assessments include frequency and severity of adverse events and changes in laboratory parameters as a measure of safety; health-related quality of life; and plasma biomarker studies that will focus on predictive biomarkers and drug resistance mechanisms. Results are expected in 2016.

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