CGFL CENTRE GEORGES FRANÇOIS LECLERC Ensemble, dépassons le cancer	**CRITERES DE SELECTION** **ETUDE _REGIRI**	Identité patient (coller étiquette patient)
Version 1.0 du 10/03/2015	Investigateur : Dr HENNEQUIN	Arc : Celine S 3427

VALIDATION DES CRITERES DE SELECTION

Critères d'inclusion

1. Patient must have signed a written informed consent form prior to any study specific procedures	☐ oui ☐ non
2. Patients aged ≥18 years	☐ oui ☐ non
3. Histologically confirmed diagnosis of gastro-esophageal adenocarcinomas: gastroesophageal junction (Siewert II and III) and gastric adenocarcinomas*	☐ oui ☐ non
4. Asymptomatic primary tumour (e.g. no dysphagia leading to trouble swallowing tablets, no bleeding requiring repeated blood transfusion)	☐ oui ☐ non
5. Metastatic disease	☐ oui ☐ non
6. At least one target lesion: a. Unidimensionally measurable on cross-sectional imaging b. In an area not previously irradiated	☐ oui ☐ non
7. Disease progression after a first line fluoropyrimidine and platinum agent-based chemotherapy or early recurrent disease after surgery with neo-adjuvant and/or adjuvant platinum-based chemotherapy (within 6 months of the end of chemotherapy) or progression during neo-adjuvant and/or adjuvant platinum-based chemotherapy (5-FU or 5-FU prodrugs combined with cisplatin or oxaliplatin). For example, docetaxel combined with FOLFOX, PD-L1/PD1 inhibitors combined with FOLFOX or LV5-FU2-cisplatin or 5-FU-cisplatin are acceptable prior therapies	☐ oui ☐ non
8. ECOG performance status ≤1	☐ oui ☐ non
9. Life expectancy >3 months	☐ oui ☐ non
10. lipase ≤1.5 x ULN	☐ oui ☐ non
11. Total bilirubin ≤1.5 x ULN	☐ oui ☐ non
12. Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) ≤3.0 x ULN (≤5 x ULN for patients with liver metastasis)	☐ oui ☐ non

13. Alkaline phosphatase (ALP) ≤2.5 x ULN (≤5.0 x ULN for patients with liver or bone metastases)	☐ oui ☐ non
14. Platelet count ≥100,000/mm3; haemoglobin (Hb) ≥9 g/dL; absolute neutrophil count (ANC) ≥1,500/ mm3. The use of blood transfusion(s) to meet the inclusion criteria will not be allowed	☐ oui ☐ non
15. International normalized ratio (INR) ≤1.5 x ULN and partial thromboplastin time (PTT) or activated partial thromboplastin time (aPTT) ≤1.5 x ULN unless receiving treatment with therapeutic anticoagulation. Patients being treated with anticoagulant, e.g., heparin, are eligible if there is no evidence of an underlying abnormality with these parameters. Close monitoring of at least weekly evaluations will be performed until INR and PTT are stable based on a pre-dose measurement as defined by the local standard of care	☐ oui ☐ non
16. Creatinine clearance (CLcr) ≥30 mL/min estimated by Cockcroft-Gault equation	☐ oui ☐ non
17. Women of childbearing potential and men must agree to use adequate contraception during the study and for at least 3 months after the last study drug administration.	☐ oui ☐ non
18. Patients affiliated to the social security system	☐ oui ☐ non

Critères de non inclusion

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1.Symptomatic brain metastases or carcinomatous meningitis	☐ oui ☐ non
2. Bone-only metastasis	☐ oui ☐ non
3. Known and documented UGT1A1 deficiency	☐ oui ☐ non
4. History of Gilbert's syndrome	☐ oui ☐ non
5. Previous or concurrent cancer with a distinct primary site, other than oesogastric cancer, within 5 years prior to randomisation (except for curatively treated cervical cancer in situ, non-melanoma skin cancer, and superficial bladder tumours)	☐ oui ☐ non
6. Persistent proteinuria >3.5 g/24 h measured by urine protein-creatinine ratio from a random urine sample (Grade ≥3, NCI-CTCAE v 5.0)	☐ oui ☐ non
7. Interstitial lung disease with ongoing signs and symptoms at inclusion	☐ oui ☐ non
8. Known hypersensitivity to any of the study drugs, study drug classes, or excipients	☐ oui ☐ non
9. Non-healing wound, non-healing ulcer, or non-healing bone fracture	☐ oui ☐ non
10. Patients with evidence or history of any bleeding diathesis, irrespective of severity	☐ oui ☐ non
11. Any haemorrhage or bleeding event grade ≥3 (NCI-CTCAE v.5.0) within 4 weeks before starting of the study treatment	☐ oui ☐ non

12. Arterial or venous thrombotic or embolic events such as cerebrovascular accident (including transient ischemic attacks), deep vein thrombosis or pulmonary embolism within 6 month before starting the study treatment (except for adequately treated catheter-related venous thrombosis occurring more than one month before the start of study medication)	☐ oui ☐ non
13. Previous major surgical procedure, significant traumatic injury, or radiotherapy within the 4 weeks before inclusion	☐ oui ☐ non
14. Uncontrolled hypertension (systolic blood pressure >140 mmHg or diastolic pressure >90 mmHg) despite optimal medical management. Congestive heart failure ≥New York Heart Association (NYHA) class 2	☐ oui ☐ non
15. Unstable angina (angina symptoms at rest), new-onset angina (that started within the last 3 months)	☐ oui ☐ non
16. Myocardial infarction less than 6 months before starting the study treatment	☐ oui ☐ non
17. Uncontrolled cardiac arrhythmias	☐ oui ☐ non
18. History of epileptic seizures requiring long-term anticonvulsant therapy	☐ oui ☐ non
19. History of organ transplantation with use of immunosuppression therapy	☐ oui ☐ non
20. Ongoing bacterial or fungal infection (grade >2 by NCI-CTCAE v.5.0)	☐ oui ☐ non
21. Known history of human immunodeficiency virus (HIV) infection	☐ oui ☐ non
22. Active hepatitis B or C, or chronic hepatitis B or C requiring treatment with antiviral therapy	☐ oui ☐ non
23. Use of CYP 3A4 inducers or inhibitors	☐ oui ☐ non
24. Pregnant and breast-feeding women	☐ oui ☐ non
25. Bowel malabsorption or extended bowel resection that could affect the absorption of regorafenib, occlusive syndrome, inability to take oral medications	☐ oui ☐ non
26. Inflammatory bowel disease with chronic diarrhoea	☐ oui ☐ non
27. Participation in another clinical trial within the 30 days before inclusion	☐ oui ☐ non
28. Concurrent treatment with another investigational product or anticancer therapy (other than irinotecan or regorafenib)	☐ oui ☐ non
29. Concomitant treatment with hypericum or live attenuated vaccines	
30. Gastro-intestinal fistula or perforation	
31. Person kept in detention or incapable of giving consent	☐ oui ☐ non
32. Patient unwilling or unable to comply with the medical follow-up required by the study because of geographic, social, or psychological reasons	☐ oui ☐ non

Date : _____

Signature de l'investigateur : _____