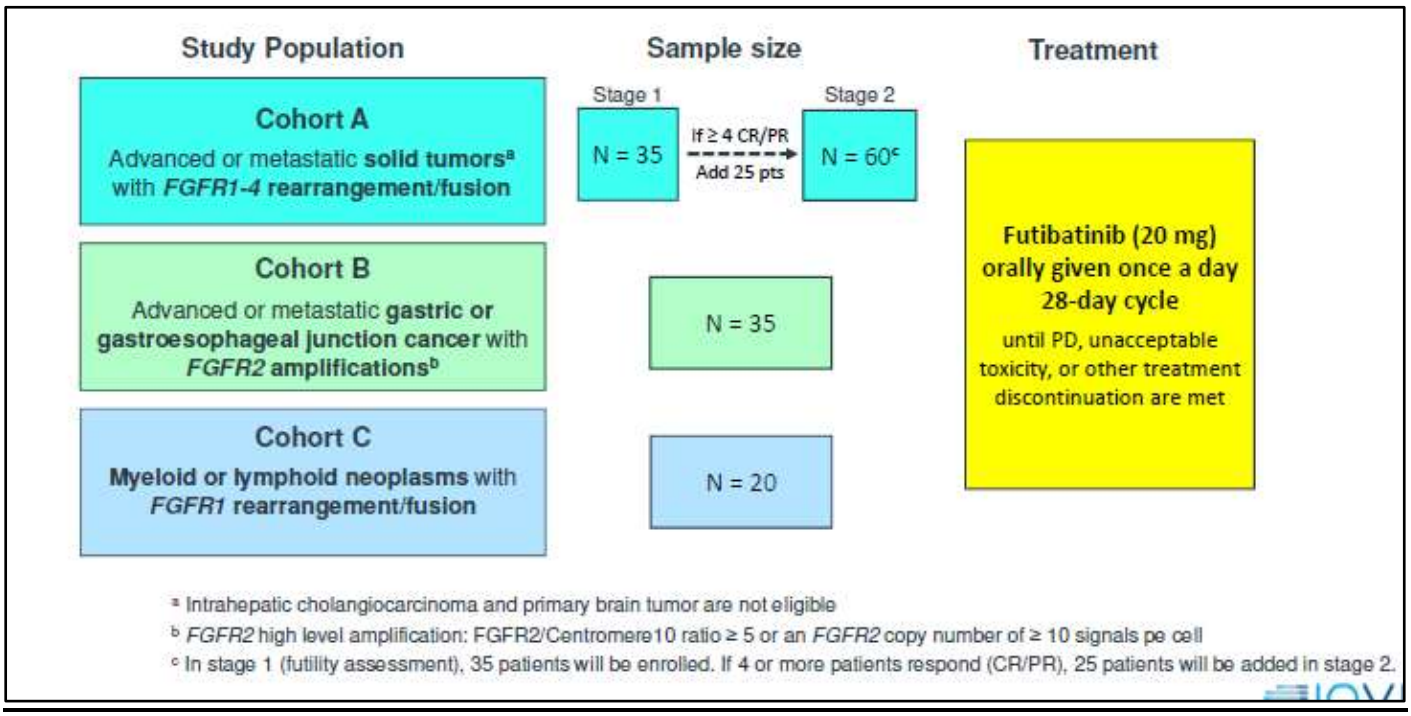
CGFL Centre Georges François Leclerc Ensemble, dépassons le cancer	**CRITERES DE SELECTION** **ETUDE TAS-120-202**	Identité patient (coller étiquette patient)
Version 1.0 du 27/10/2021	Investigateur en charge du patient : …….. PI : **Pr GHIRINGHELLI** Mail : fghiringhelli@cgfl.fr *A contacter pour adresser/inclure patient externe au CGFL*	Arc : Hélène DUROUX Poste : 3460

« TAS 120 »
Etude du futibatinib chez des patients atteints d'altération de FGFR.



VALIDATION DES CRITERES DE SELECTION

Critères d'inclusion :

1. Provide written informed consent	□ oui □ non
2. ≥18 years of age (or meets the country's regulatory definition for legal adult age, whichever is greater)	□ oui □ non
3.Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1	□ oui □ non
4. Has recovered from the acute toxic effects of prior anticancer therapy to baseline or Grade 1 (except toxicities which are not clinically significant such as alopecia)	□ oui □ non
5. Known *FGFR* aberration status and tumor type that meet all of the criteria for 1 of the following cohorts:	□ oui □ non

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a : **Cohort A** i. Histologically-confirmed, locally-advanced, advanced, or metastatic solid tumors harboring a *FGFR1-4* rearrangement determined in tumor tissue using nextgeneration sequencing (NGS), fluorescence in situ hybridization (FISH), or other assays that can determine gene rearrangements in tumor tissues. Patients with primary brain tumor or intrahepatic cholangiocarcinoma are not eligible. ii. Measurable disease per RECIST 1.1 iii. Had disease progression/recurrence after standard treatment for their advanced or metastatic cancer b : **Cohort B** i. Histologically-confirmed, locally-advanced, advanced, or metastatic gastric or GEJ cancer harboring a *FGFR2* amplification. The tumor must have an FGFR2/CEN10 ratio of ≥5 or an *FGFR2* copy number ≥10 signals per cell determined in tumor tissue using NGS, FISH, or other assays that can determine gene amplifications in tumor tissues. ii. Measurable disease per RECIST 1.1 iii. Received at least 2 prior systemic regimens for advanced/metastatic disease iv. Experienced disease progression/recurrence during or after the most recent prior systemic treatment for advanced/metastatic gastric or GEJ cancer	
6. Has archival or fresh tumor tissue (preferably in block format) available to send to central laboratory.	□ oui □ non
7. Adequate organ function as defined by the following criteria: **a. Cohorts A and B:** i. Absolute neutrophil count (ANC) ≥ 1.0 × 109/L ii. Platelet count ≥ 75,000/mm3 (≥ 75 × 109/L) iii. Hemoglobin ≥ 9.0 g/dL iv. ALT and aspartate aminotransferase (AST) ≤ 3.0 × upper limit of normal (ULN); if liver function abnormalities are due to underlying liver metastasis, AST and ALT ≤ 5.0 × ULN. v. Total bilirubin ≤ 1.5 × ULN, or ≤ 3.0 × ULN for patients with Gilbert's syndrome. vi. Creatinine clearance (CrCl) (calculated or measured value): ≥40 mL/min. For calculated CrCl, use the Cockcroft-Gault formula (Section 6). vii. Phosphorus < 1.5 ULN	□ oui □ non
8. Women of child-bearing potential (WOCBP) must have a negative serum pregnancy test prior to administration of the first dose of futibatinib. Female patients are not considered	□ oui □ non

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to be of child-bearing potential if they are post-menopausal (no menses for 12 months without an alternative medical cause) or permanently sterile (hysterectomy, bilateral salpingectomy, or bilateral oophorectomy).	
9. Both males and females of reproductive potential must agree to use effective birth control during the study prior to the first dose and for 90 days after the last dose or longer based on local requirements.	□ oui □ non
10. Ability to take medications orally (feeding tube is not permitted).	□ oui □ non
11. Willing and able to comply with scheduled visits and study procedures.	□ oui □ non

Critères de non inclusion :

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1. Currently receiving an investigational drug in a clinical trial or participating in any other type of medical research judged not to be scientifically or medically compatible with this study. If a patient is currently enrolled in a clinical trial involving non-approved use of a device, then agreement with the investigator and Taiho Medical monitor is required to establish eligibility.	□ oui □ non
2. History and/or current evidence of any of the following disorders: a. Non-tumor related alteration of the calcium-phosphorus homeostasis that is considered clinically significant in the opinion of the Investigator. b. Ectopic mineralization/calcification, including but not limited to soft tissue, kidneys, intestine, or myocardia and lung, considered clinically significant in the opinion of the Investigator. c. Retinal or corneal disorder confirmed by retinal/corneal examination and considered clinically significant in the opinion of the Investigator.	□ oui □ non
3. Corrected QT interval using Fridericia's formula (QTcF) >470 msec. Patients with an atrioventricular pacemaker or other condition (for example, right bundle branch block) that renders the QT measurement invalid are an exception and the criterion does not apply.	□ oui □ non
4. Treatment with any of the following within the specified time frame prior to the first dose of futibatinib: a. Major surgery within 4 weeks (surgical incision should be fully healed) b. Radiotherapy for extended field within 4 weeks or limited field radiotherapy within 2 weeks c. A drug that has not received regulatory approval for any indication within 14 or 21 days of treatment for a nonmyelosuppressive or myelosuppressive agent, respectively	□ oui □ non
5. Received strong inhibitors and inducers of CYP3A4 within 2 weeks	□ oui □ non

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6. Prior treatment with an FGFR inhibitor	□ oui □ non
7. A serious illness or medical condition(s) including, but not limited to, the following: a. Known acute systemic infection b. Myocardial infarction, severe/unstable angina, or symptomatic congestive heart failure within the previous 6 months c. History or current evidence of uncontrolled ventricular arrhythmia d. Chronic diarrhea diseases considered to be clinically significant in the opinion of the Investigator e. Congenital long QT syndrome, or any known history of torsade de pointes, or family history of unexplained sudden death f. Other severe acute or chronic medical or psychiatric condition or laboratory abnormality that may increase the risk associated with study participation or futibatinib administration, or may interfere with the interpretation of study results, and in the judgment of the Investigator would make the patient inappropriate for entry into this study	□ oui □ non
8. Active central nervous system (CNS) metastasis and/or carcinomatous meningitis. Patients with previously treated brain metastases that are clinically and radiologically stable (for at least 4 weeks prior to enrollment) are eligible.	□ oui □ non
9. Known additional malignancy that is progressing or has required active treatment within the past 2 years. Patients with basal cell carcinoma of the skin, squamous cell carcinoma of the skin, or carcinoma in situ (eg, breast carcinoma, cervical cancer in situ) that have undergone potentially curative therapy are not excluded.	□ oui □ non
10. Pregnant or breastfeeding.	□ oui □ non
	□ oui □ non

Date : _____

Signature de l'investigateur : _____