	CRITERES DE SELECTION ETUDE TAS-120-202	Identité patient (coller étiquette patient)
Version 1.0 du 10/03/2015	Investigateur :	Arc : Hélène

VALIDATION DES CRITERES DE SELECTION

Critères d'inclusion

1. Provide written informed consent	<input type="checkbox"/> oui <input type="checkbox"/> non
2. ≥18 years of age (or meets the country's regulatory definition for legal adult age, whichever is greater)	<input type="checkbox"/> oui <input type="checkbox"/> non
3. Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1	<input type="checkbox"/> oui <input type="checkbox"/> 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)	<input type="checkbox"/> oui <input type="checkbox"/> non
5. Known <i>FGFR</i> aberration status and tumor type that meet all of the criteria for 1 of the following cohorts: a : Cohort A i. Histologically-confirmed, locally-advanced, advanced, or metastatic solid tumors harboring a <i>FGFR1-4</i> 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 <i>FGFR2</i> amplification. The tumor must have an <i>FGFR2/CEN10</i> ratio of ≥5 or an <i>FGFR2</i> 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	<input type="checkbox"/> oui <input type="checkbox"/> non
6. Has archival or fresh tumor tissue (preferably in block format) available to send to central laboratory.	<input type="checkbox"/> oui <input type="checkbox"/> non

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<p>7. Adequate organ function as defined by the following criteria:</p> <p>a. Cohorts A and B:</p> <p>i. Absolute neutrophil count (ANC) $\geq 1.0 \times 10^9/L$</p> <p>ii. Platelet count $\geq 75,000/mm^3$ ($\geq 75 \times 10^9/L$)</p> <p>iii. Hemoglobin ≥ 9.0 g/dL</p> <p>iv. ALT and aspartate aminotransferase (AST) $\leq 3.0 \times$ upper limit of normal (ULN); if liver function abnormalities are due to underlying liver metastasis, AST and ALT $\leq 5.0 \times$ ULN.</p> <p>v. Total bilirubin $\leq 1.5 \times$ ULN, or $\leq 3.0 \times$ ULN for patients with Gilbert's syndrome.</p> <p>vi. Creatinine clearance (CrCl) (calculated or measured value): ≥ 40 mL/min. For calculated CrCl, use the Cockcroft-Gault formula (Section 6).</p> <p>vii. Phosphorus < 1.5 ULN</p>	<p><input type="checkbox"/> oui</p> <p><input type="checkbox"/> non</p>
<p>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 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).</p>	<p><input type="checkbox"/> oui</p> <p><input type="checkbox"/> non</p>
<p>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.</p>	<p><input type="checkbox"/> oui</p> <p><input type="checkbox"/> non</p>
<p>10. Ability to take medications orally (feeding tube is not permitted).</p>	<p><input type="checkbox"/> oui</p> <p><input type="checkbox"/> non</p>
<p>11. Willing and able to comply with scheduled visits and study procedures.</p>	<p><input type="checkbox"/> oui</p> <p><input type="checkbox"/> non</p>

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Critères de non inclusion

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.	<input type="checkbox"/> oui <input type="checkbox"/> 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.	<input type="checkbox"/> oui <input type="checkbox"/> 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.	<input type="checkbox"/> oui <input type="checkbox"/> 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	<input type="checkbox"/> oui <input type="checkbox"/> non
5. Received strong inhibitors and inducers of CYP3A4 within 2 weeks	<input type="checkbox"/> oui <input type="checkbox"/> non
6. Prior treatment with an FGFR inhibitor	<input type="checkbox"/> oui <input type="checkbox"/> 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	<input type="checkbox"/> oui <input type="checkbox"/> non



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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.	<input type="checkbox"/> oui <input type="checkbox"/> 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.	<input type="checkbox"/> oui <input type="checkbox"/> non
10. Pregnant or breastfeeding.	<input type="checkbox"/> oui <input type="checkbox"/> non
	<input type="checkbox"/> oui <input type="checkbox"/> non

Date : _____

Signature de l'investigateur : _____