# Essai Clinique

Généré le 07 mai 2024 à partir de

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| Titre | Étude à répartition aléatoire et à double insu visant à évaluer l'efficacité et l'innocuité du cabozantinib (XL184) en comparant les doses journalières de 60 mg et 140 mg chez des patients atteints d'un cancer médullaire, métastatique et progressif de la thyroïde |
| Protocole ID | XL184-401 |
| ClinicalTrials.gov ID | NCT01896479 |
| Type(s) de cancer | Thyroïde |
| Phase | Phase IV |
| Type étude | Traitement |
| Médicament | Cabozantinib |
| Institution | CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE<br>HOPITAL FLEURIMONT<br>3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4 |
| Ville | Sherbrooke |
| Investigateur principal | Dre Marie-France Langlois |
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| Statut | Fermé |
| But étude | The objective of this study is to evaluate the efficacy and safety of oral cabozantinib at a 60 mg dose compared with a 140 mg dose in subjects with progressive, metastatic MTC. It will test if the lower dose results in similar progression free survival (PFS) and overall response rate (ORR) with fewer adverse events compared to the PFS, ORR and adverse events found in previous clinical trials of 140 mg. |
| Critères d'éligibilité | • The subject has a histologically confirmed diagnosis of MTC.<br>• All subjects will need to be tested for RET mutational status. If subjects do not have documentation confirming they have a RET mutation, a sample of their tumor (taken either during screening or from a procedure within 6 months prior to randomization) will need to be tested.<br>• The subject has measurable disease per RECIST 1.1 that is metastatic as determined by the investigator based upon computerized tomography (CT), magnetic resonance imaging (MRI), PET scan, bone scan, or X-ray taken within 28 days before randomization.<br>• The subject has documented worsening of disease (progressive disease) at screening as compared with a previous CT, PETor MRI scan, bone scan, or X-ray as determined by the investigator per RECIST 1.1 on qualifying screening images taken within 28 days prior to randomization as compared to previous images taken within 14 months before the qualifying screening images.<br>• The subject has recovered to baseline or CTCAE v4.0 (Common Terminology Criteria for Adverse Events, version 4.0) ≤ Grade 1 from toxicities related to any prior treatments, unless AE(s) are clinically non-significant and/or stable on supportive therapy.<br>• The subject has an Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 1 at screening.<br>• The subject has adequate organ and marrow function<br>• The subject is capable of understanding and complying with the protocol requirements and has signed the informed consent document.<br>• Sexually active fertile subjects and their partners must agree to use medically accepted methods of contraception (eg, barrier methods, including male condom, female condom, or diaphragm with spermicidal gel) during the course of the study and for 4 months after the last dose of study treatment. |

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| Critères d'exclusion | • The subject has previously received cabozantinib.<br>• Receipt of any type of small molecule kinase inhibitor or hormonal therapy within 28 days or 5 half-lives of the compound or active metabolites, whichever is shorter, before randomization.<br>• Receipt of any systemic anti-tumor therapy within 28 days of randomization (42 days for nitrosoureas or/ mitomycin C).<br>• Receipt of any other type of investigational agent within 28 days of randomization.<br>• Receipt of radiation therapy within 28 days (14 days for radiation for bone metastases) of randomization or radionuclide treatment within 42 days of randomization. Subject is ineligible if there are any clinically relevant ongoing complications from prior radiation therapy.<br>• The subject has untreated and/or active (progressing or requiring anticonvulsants or corticosteroids for symptomatic control) central nervous system (CNS) metastasis. Must have completed radiation therapy ≥ 28 days prior to randomization and be stable without corticosteroids or anti-convulsant treatment for ≥ 10 days.<br>• Treatment at therapeutic doses with oral anticoagulants or platelet inhibitors (examples are warfarin and clopidogrel).<br>• The subject has uncontrolled, significant intercurrent illness including, but not limited to, cardiovascular disorders, gastrointestinal disorders, active infections, non-healing wounds, recent surgery.<br>• Corrected QT interval calculated by the Fridericia formula (QTcF) > 500 ms within 28 days before randomization.<br>• The subject is unable to swallow multiple tablets or capsules.<br>• The subject has a previously identified allergy or hypersensitivity to components of the study treatment formulation.<br>• The subject is pregnant or breastfeeding.<br>• The subject has had a diagnosis of another malignancy within 2 years before randomization, except for superficial skin cancers, or localized, low-grade tumors deemed cured and not treated with systemic therapy. |