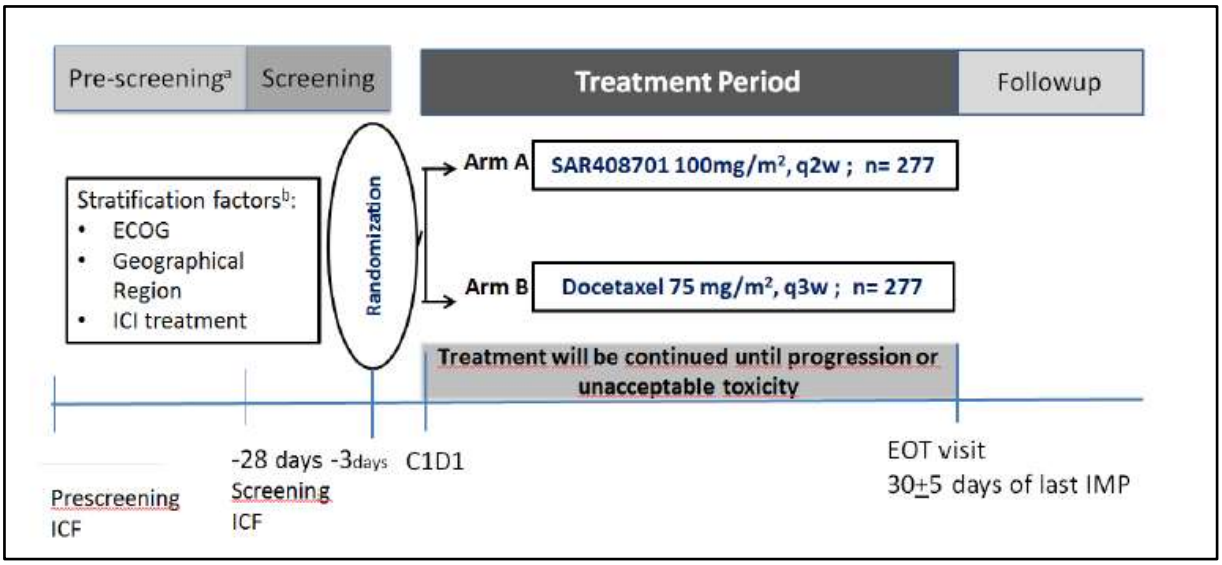
CGFL CENTRE GEORGES FRANÇOIS LECLERC Ensemble, dépassons le cancer	**CRITERES DE SELECTION** **ETUDE CARMEN**	Identité patient (coller étiquette patient)
Version 1.0 du 25/10/2021	Investigateur en charge du patient : …….. PI : **Dr Laure FAVIER** Mail : lfavier@cgfl.fr *A contacter pour adresser/inclure patient externe au CGFL*	Arc : **Anais BOTTE** Poste : 3466

« CARMEN »

Étude de phase 3 randomisée, en ouvert évaluant le SAR408701 par rapport au docétaxel chez des patients précédemment traités, atteints d'un cancer bronchique non à petites cellules non épidermoïde métastatique avec tumeurs CEACAM5 positives.



VALIDATION DES CRITERES DE SELECTION

Critères d'inclusion

I 01. Participant must be ≥ 18 years of age (or country's legal age of majority if >18 years) at the time of signing the informed consent.	□ oui □ non
I 02. Histologically or cytologically proven diagnosis of non-squamous NSCLC metastatic disease at study entry; meeting all 3 of the following criteria: a) Having progressive disease during or after platinum-based chemotherapy (at least 2 cycles). Maintenance therapy following platinum-based chemotherapy is not considered as a separate regimen. Adjuvant/neoadjuvant treatment for a patient who had a relapse with metastatic disease during or within 6 months of completion of treatment will be considered as first line treatment. AND b) Having progressive disease during or after one immune checkpoint inhibitor (anti-	□ oui □ non

PD1/PD-L1); this could be given as monotherapy or in combination with platinum-based chemotherapy (whatever the order). AND c) Participant with EGFR sensitizing mutation or BRAF mutation or ALK/ROS alterations must be able to demonstrate progression of the disease on approved treatments for these conditions, in addition to platinum-based chemotherapy and immune checkpoint inhibitor.	
I 03. Participants with CEACAM5 expression of ≥2+ in intensity in archival tumor sample (or if not available fresh biospy sample) involving at least 50 % of the tumor cell population as demonstrated prospectively by a centrally assessed ICH assay. At least 7 × 4 µm slides from FFPE tumor tissue are required. If less material is available, patient could still be eligible after discussion with the Sponsor who will assess and confirm that there is sufficient relevant material for key evaluations.	□ oui □ non
I 04. At least one measurable lesion by RECIST v1.1 as determined by local site investigator /radiology assessment. Irradiated lesion can be considered measurable only if progression has been demonstrated on irradiated lesion.	□ oui □ non
I 05. Eastern Cooperative Oncology Group (ECOG) performance status 0-1.	□ oui □ non
I 06. Male or female Contraceptive use by men or women should be consistent with local regulations regarding the methods of highly effective contraception for those participating in clinical studies. a) Male participants Male participants: A male participant must agree to use contraception methods (see Appendix 5, Section 10.5) during the intervention period and for at least 6 months after the last dose of study intervention. Men being treated with docetaxel should be advised to seek advice on conservation of sperm prior to treatment. b) Female participants Female participants: A female participant is eligible to participate if she is not pregnant (see Appendix 5, Section 10.5), not breastfeeding, and at least one of the following conditions applies: Not a woman of childbearing potential (WOCBP) as defined in Appendix 5 (Section 10.5). OR A WOCBP who agrees to follow the contraceptive guidance in Appendix 5 (Section 10.5) during the intervention period and for at least 7 months after the last dose of study intervention.	□ oui □ non

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I 07. Capable of giving signed informed consent as described in Appendix 1, Section 10.1.3, which includes compliance with the requirements and restrictions listed in the ICF and in this protocol.	□ oui □ non

Critères de non inclusion :

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E 01. Untreated brain metastases and history of leptomeningeal disease. Patients with previously treated brain metastases may participate provided they are stable (ie, without evidence of progression) by imaging performed at least 4 weeks after CNS-directed treatment and at least 2 weeks prior to the first administration of study intervention, and any neurologic symptoms have returned to baseline; and there is no evidence of new or enlarging brain metastases; and the patient does not require any systemic corticosteroids for management of brain metastases within 2 weeks prior to the first dose of study intervention.	□ oui □ non
E 02. Significant concomitant illnesses, including all severe medical conditions which, in the opinion of the investigator or Sponsor, would impair the patient's participation in the study or interpretation of the results.	□ oui □ non
E 03. History within the last 3 years of an invasive malignancy other than the one treated in this study, with the exception of resected/ablated basal or squamous-cell carcinoma of the skin or carcinoma in situ of the cervix, or other local tumors considered cured by local treatment.	□ oui □ non
E 04. History of known acquired immunodeficiency syndrome (AIDS) related illnesses or known HIV disease requiring antiretroviral treatment, or active hepatitis A, B (defined as either positive HBs antigen or positive hepatitis B viral DNA test above the lower limit of detection of the assay), or C (defined as a known positive hepatitis C antibody result and known quantitative HCV RNA results greater than the lower limits of detection of the assay) infection. HIV serology at screening will be tested only for participants enrolled in German sites and any countries where mandatory as per local requirements.	□ oui □ non
E 05. Non-resolution of any prior treatment related toxicity to < Grade 2 according to NCI CTCAE V5.0, except for alopecia, vitiligo and active thyroiditis controlled with hormonal replacement therapy.	□ oui □ non
E 06. Unresolved corneal disorders or any previous corneal disorder that considered by ophthalmologist that patient may have higher risk of drug induced keratopathy. The use of contact lenses is not permitted. Patients using contact lenses who are not willing to stop wearing them for the duration of the study intervention.	□ oui □ non
E 07. Medical conditions requiring concomitant administration of medications with narrow therapeutic window, metabolized by CYPs (See Appendix 9) and for which a dose reduction cannot be considered.	□ oui □ non
E 08. Medical conditions requiring concomitant administration of strong CYP3A inhibitor (see Appendix 10), unless it can be discontinued at least 2 weeks before first administration of	□ oui □ non

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study intervention	
E 09. Concurrent treatment with any other anticancer therapy.	□ oui □ non
E 10. Prior treatment with docetaxel	□ oui □ non
E 11. Prior therapy targeting CEACAM5	□ oui □ non
E 12. Prior maytansinoid treatment (DM1 or DM4 antibody drug conjugate)	□ oui □ non
E 13. Washout period before the first administration of study intervention of less than 3 weeks or less than 5 times the half-life, whichever is shorter, for prior antitumor therapy (chemotherapy, targeted agents, immunotherapy and radiotherapy, or any investigational treatment.	□ oui □ non
E 14. Any major surgery within the preceding 3 weeks of the first study intervention administration.	□ oui □ non
E 15. Contraindication to use of corticosteroid premedication	□ oui □ non
E 16. Previous enrollment in this study and current participation in any other clinical study involving an investigational study treatment or any other type of medical research	□ oui □ non
E 17. Poor organ function as defined by any one of the following: • Serum creatinine >1.5 × ULN or 1.0-1.5 x ULN with eGFR < 60 mL/min/1.73m2 as estimated using a MDRD formula. • Total bilirubin > 1.0 x ULN. • AST, ALT > 2.5 × ULN or AST, ALT > 1.5 × ULN concomitant with ALP > 2.5 × ULN. ALP >5 × ULN with normal ALT/AST for patients with bone metastases. • Neutrophils <1.5 × 109/L or platelet count < 100 × 109/L or hemoglobin <9 g/dL	□ oui □ non
E 18. Individuals accommodated in an institution because of regulatory or legal order; prisoners or subjects who are legally institutionalized	□ oui □ non
E 19. Any country-related specific regulation that would prevent the subject from entering the study - (country specific requirements)	□ oui □ non
E 20. Participant not suitable for participation, whatever the reason, as judged by the Investigator, including medical or clinical conditions, or participants potentially at risk of noncompliance to study procedures	□ oui □ non
E 21. Participants who are dependent on the Sponsor or Investigator (in conjunction with section 1.61 of the ICH-GCP Ordinance E6)	□ oui □ non
E 22. Participants are employees of the clinical study site or other individuals directly involved in the conduct of the study, or immediate family members of such individuals	□ oui □ non

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E 23. Any specific situation during study implementation/course that may raise ethics considerations	□ oui □ non
E 24. Hypersensitivity to any of the study interventions, or components thereof (EDTA), or drug (paclitaxel, polysorbate 80) or other allergy that, in the opinion of the Investigator, contraindicates participation in the study	□ oui □ non
E 25. Patients treated in advanced stage with any further chemotherapy/immunotherapy in addition to the therapies defined in I02	□ oui □ non

Date : _____

Signature de l'investigateur : _____