Essai Clinique

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Titre	Une étude de phase I/II avec escalade de dose et expansion ayant pour but d'évaluer la sécurité, la pharmacocinétique, la pharmacodynamique et l'activité clinique du GSK525762 associé au fulvestrant chez des patientes atteintes d'un cancer du sein ER+
Protocole ID	GSK201973
ClinicalTrials.gov ID	NCT02964507
Type(s) de cancer	Sein
Phase	Phase I-II
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	GSK525762 et Fulvestrant
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Statut	Fermé
But étude	This is a combination Phase I and Phase II study, with an aim to evaluate the combination of GSK525762 and fulvestrant in women with advanced or metastatic ER+ breast cancer, who have disease that has progressed after prior treatment with at least one line of endocrine therapy. The objectives of the study are to first identify, in open-label single-arm Phase I, a recommended Phase II dose of GSK525762 that may be combined safely with fulvestrant. Phase I will follow a modified toxicity probability interval (mTPI) design, and a sentinel group will be evaluated first for dose-limiting toxicity and further expanded to collect additional safety data. This will be followed by a double-blind, randomized controlled Phase II, to identify the clinical activity of the two study treatments when given in combination. The composition of Phase II will be selected at the end of Phase I.

Critères d'éligibilité	• Females 18 years old and greater with histologically or cytologically confirmed diagnosis of advanced or metastatic adenocarcinoma of the breast.
	• History of prior therapy that satisfies one of the following criteria:
	  • Disease that progressed during treatment or within 12 months of completion of adjuvant therapy with tamoxifen and/or an aromatase inhibitor (AI).
	  • Disease that progressed during treatment or within 1 month after the end of treatment with prior tamoxifen, AI, or cyclin-dependent kinase (CDK) 4/6 inhibitor plus letrozole, for advanced/metastatic disease.
	• Documentation of ER-positive and/or progesterone receptor (PR)-positive tumor.
	• Documentation of human epidermal growth factor receptor 2 (HER2)-negative tumor.
	• Measurable disease as per Response Evaluation Criteria in Solid Tumors (RECIST)
	• Adequate organ function as per pre-defined hematologic, hepatic, renal, and cardiac criteria.

Critères d'exclusion	• Prior therapy with more than one line of cytotoxic chemotherapy following diagnosis of advanced/metastatic disease, or disease which has progressed despite prior fulvestrant therapy. • Concomitant active malignancy other than ER+ breast cancer. • Therapeutic-dose anticoagulation must be discontinued and coagulation parameters must be normalized prior to the first dose of GSK525762 and fulvestrant. • Evidence of severe or uncontrolled systemic diseases (example, unstable or uncompensated respiratory, hepatic, renal, cardiac disease, or clinically significant bleeding episodes). • Subjects with advanced/metastatic, symptomatic, visceral spread, that are at risk of life-threatening complications in the short term including subjects with massive uncontrolled effusions, pulmonary lymphangitis, and over 50% of liver involvement in metastases. • Symptomatic or untreated leptomeningeal or brain metastases or spinal cord compression. • Cardiac abnormalities