Essai Clinique

Généré le 29 avr. 2024 à partir de http://www.geoq.info/fr/pub/essai-clinique-3307-pdf

Titre	A Presurgical Tissue-Acquisition Study to Evaluate Molecular Alterations in Human Breast Cancer Tissue Following Short-Term Exposure to the Androgen Receptor Antagonist ODM-201
Protocole ID	TRIO030
ClinicalTrials.gov ID	NCT03004534
Type(s) de cancer	Sein
Phase	Phase I
Stade	Adjuvant
Type étude	Traitement
Médicament	ODM-201
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Statut	Fermé
But étude	The purpose of this study is to evaluate the effect of short-term treatment with ODM-201 on breast cancer cells (i.e., how the treatment may change the genes or proteins in breast cancer cells) and to evaluate its safety and the way it is tolerated by subjects. The intent is to study these changes in order to have a better understanding of the potential use of ODM-201 for women with EBC, know which patients are likely or unlikely to respond to this treatment, and determine how ODM-201 may be combined with other anti-cancer drugs.

Critères d'éligibilité	• Signed and dated PICF obtained prior to initiation of any study-specific procedure and treatment.
	• Female ≥ 18 years old.
	• Histologically proven invasive breast carcinoma (through either a core needle biopsy or an incisional biopsy) for which surgery is indicated as the primary treatment modality.
	• Known ER, PgR and HER2 statuses.
	• Tumor must be confined to either the breast or to the breast and ipsilateral axilla (Note: subjects with multifocal/multicentric tumors are eligible). Subject must have (according to TNM 7th edition rules):
	  • T1 with T ≥1.5cm, T2 or T3 by at least one radiographic or clinical measurement
	  • Either clinically positive (N1 only) or clinically negative axillary nodes (N0)
	  • M0
	• Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0 or 1.
	• Adequate organ function within 28 days prior to enrollment, as defined by the following criteria:
	  • Hematology: Haemoglobin ≥ 9.0 g/dl; ANC ≥ 1.5 × 109/L; Platelet count ≥ 100 × 109/L
	  • Liver function: ALT and AST ≤ 2.5 × ULN; Total bilirubin ≤ 1.5 × ULN (or ≤ 3 times ULN for subjects with documented Gilbert's syndrome or for whom indirect bilirubin concentrations suggest an extra-hepatic source of elevation)
	  • Renal function: Creatinine ≤ 2.0 × ULN
	• No more than 42 days should elapse from the day study-specific tumor sample is taken at initial diagnosis (or subsequent procedure) to the time of the first intake of ODM-201.
	• Women of childbearing potential (WoCBP)* must agree to use acceptable non-hormonal contraceptive methods of birth control from the day of the screening pregnancy test and up to 3

	months after the last intake of ODM-201.
Critères d'exclusion	• Any T0, Tis, T1 < 1.5 cm, T4; or N2-3; or M1 BC. • Bilateral invasive BC. • Subject that underwent excisional biopsy of the primary tumor. • Medical indication or subject desire to undergo BC surgery prior to completing at least 14 days of treatment with ODM-201. • Prior or concurrent systemic anticancer therapy for BC (immunotherapy, hormonotherapy, biologic/targeted therapy, chemotherapy, investigational agents). • Prior or concurrent ipsilateral radiation therapy for invasive or noninvasive BC. • Prior treatment or preventative use of any hormonal agent such as aromatase inhibitors (AI), fulvestrant, raloxifene, tamoxifen or other SERM, or with any other hormonal agent used for the treatment or prevention of BC or for any other indication (e.g. osteoporosis). • Concurrent use of ovarian hormone replacement therapy. Prior treatment should be stopped at least 28 days prior to registration. • Prior or concurrent treatment with AR antagonists or CYP17 enzyme inhibitor. • Use of other investigational drug within 28 days of enrollment. • Major surgery* within 28 days before enrollment. • Any concurrent or previous malignancy within 5 years prior to enrollment except for basal or squamous skin cancer, or carcinoma in situ of the cervix, or other non-invasive/in-situ neoplasm, all of which must have been adequately and radically treated. A subject with previous history of invasive malignancy (other than adequately and radically treated basal or squamous skin cancer) is eligible provided that she has been disease free for more than 5 years. • Severe or uncontrolled concurrent disease, infection or comorbidity. • Known active viral hepatitis, HIV or chronic liver disease. • Other serious illness or medical condition within 6 months before enrollment, including any of the following: Concurrent congestive heart failure NYHA Class III or IV, severe/unstable angina pectoris, myocardial infarction, uncontrolled hypertension, coronary/peripheral artery bypass graft, high-risk uncontrolled arrhythmias, stroke. • Any contraindication to oral agents or gastrointestinal disorder or procedure which expects to interfere significantly with absorption of protocol treatment. • History or current evidence of any condition, therapy, or laboratory abnormality that might confound the results of the trial, interfere with the subject's participation for the full duration of the trial, or is not in the best interest of the subject to participate, in the opinion of the treating investigator. • Known psychiatric or substance abuse disorders that would interfere with cooperation with the requirements of the trial. • Known allergy to ODM-201 or any of the excipients. • Pregnant or lactating subjects. * Note: Major surgery defined as requiring a general anesthesia or respiratory assistance; involving openings into the great cavities of the body, organs removed, or normal anatomy altered; implying risks of severe hemorrhage; implying risk for life of the patient or severe disability.