# CONTESSA - (dernière mise à jour : 14/10/2019)

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## Informations générales

**Titre de l'étude** : Etude internationale, multicentrique, randomisée, de phase 3, comparant l'association du tésétaxel avec une dose réduite de capécitabine versus la capécitabine monothérapie chez des patients atteints d'un cancer du sein localement avancé ou métastatique, HER2 négatif, exprimant les récepteurs hormonaux et préalablement traités par un taxane

**Traitement** : Métastasique ou localement avancé

**Type d'étude** : Hors ciblage moléculaire

**Phase** : III **Stade** : Métastatique **Ligne(s)** : 1, 2

**Schéma** : This is a multinational, multicenter, randomized, open-label, parallel group Phase 3 study. The primary objective is to compare the efficacy of tesetaxel plus a reduced dose of capecitabine versus the approved dose of capecitabine alone based on PFS, as assessed by an Independent Radiologic Review Committee (IRC), in patients with HER2 negative, HR positive, LA/MBC previously treated with a taxane in the neoadjuvant or adjuvant setting.

- Patients randomly assigned to Arm A (tesetaxel plus a reduced dose of capecitabine) will be administered:
-> Tesetaxel (27 mg/m2) orally once every 21 days on Day 1 of each 21-day cycle; and
-> Capecitabine (825 mg/m2) orally twice daily (in the morning and evening after a meal, for a total daily dose of 1,650 mg/m2) beginning with the evening dose on Day 1 through the morning dose on Day 15 of each 21-day cycle

- Patients randomly assigned to Arm B (approved dose of capecitabine alone) will be administered:
-> Capecitabine (1,250 mg/m2) orally twice daily (in the morning and evening after a meal, for a total daily dose of 2,500 mg/m2), beginning with the evening dose on Day 1 through the morning dose on Day 15 of each 21-day cycle Dose modifications for tesetaxel and/or capecitabine are described in the Study protocol.

Patients will be treated until documentation of progressive disease (PD), evidence of unacceptable toxicity, or other decision to discontinue treatment.

## Spécialités / Localisations

**Spécialité n°1** : Seins, organes génitaux de la femme

**CIM10 - Localisation n°1** : **C50** - Tumeur maligne du sein

## Critères

**Critères d'inclusion** : - Female or male patients at least 18 years of age
- Histologically or cytologically confirmed breast cancer
- HER2 negative disease based on local testing: American Society of Clinical Oncology/College of American Pathologists (ASCO/CAP) guidelines should be utilized for assessing HER2 status.
- HR (ER and/or PgR) positive disease based on local testing: ASCO/CAP guidelines should be utilized for assessing HR status.
- Measurable disease per RECIST 1.1 or bone-only disease with lytic component. Patients with bone-only metastatic cancer must have a lytic or mixed lytic-blastic lesion that can be accurately assessed by computerized tomography (CT) or magnetic resonance imaging (MRI). Patients with bone-only disease without a lytic component (ie, blastic-only metastasis) are not eligible.

- Eastern Cooperative Oncology Group (ECOG) performance status 0, 1, or 2
- Prior therapy (at least one completed dose) with a taxane-containing regimen in the neoadjuvant or adjuvant setting
- Prior therapy with an anthracycline-containing regimen in the neoadjuvant, adjuvant, or metastatic setting, where indicated by local regulation or Investigator judgment.
- Prior endocrine therapy with or without a CDK 4/6 inhibitor unless endocrine therapy is not indicated (ie, short relapse-free interval while on adjuvant endocrine therapy [endocrine resistance]; rapidly progressing disease/visceral crisis; or endocrine intolerance). Any targeted therapies approved for HER2 negative, HR positive MBC, including everolimus, are permitted as prior therapy. There is no limit to the number of prior endocrine therapies.
- Documented disease recurrence or disease progression of: (a) locally advanced disease that is not considered curable by surgery and/or radiation; or (b) metastatic disease.
- Adequate hematologic, hepatic, and renal function, as evidenced by:
-> Absolute neutrophil count (ANC) >= 1,500/?L without colony-stimulating factor support
-> Platelet count >= 100,000/?L
-> Hemoglobin >= 10 g/dL without need for hematopoietic growth factor or transfusion support
-> Total bilirubin < 1.5 × upper limit of normal (ULN); does not apply to patients with Gilbert's syndrome
-> Alanine aminotransferase (ALT) < 3 × ULN unless hepatic metastases are present, then < 5 × ULN
-> Aspartate aminotransferase (AST) < 3 × ULN unless hepatic metastases are present, then < 5 × ULN
-> Alkaline phosphatase < 2.5 × ULN unless hepatic metastases are present, then < 5 × ULN
-> Calculated creatinine clearance >= 50 mL/min
-> Serum albumin >= 3.0 g/dL
-> Prothrombin time (PT) < 1.5 × ULN or international normalized ratio (INR) < 1.3 and partial thromboplastin time (PTT) < 1.5 × ULN; unless the patient is on a therapeutic anticoagulant
- Complete recovery to baseline or Grade 1 per National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 5.0 from adverse effects of prior surgery, radiotherapy, endocrine therapy, and other therapy, as applicable, with the exception of Grade 2 alopecia from prior chemotherapy
- Ability to swallow an oral solid-dosage form of medication
- A negative serum pregnancy test within 7 days prior to the first dose of Study treatment in women of childbearing potential (ie, all women except those who are post menopause for >= 1 year or who have a history of hysterectomy or surgical sterilization)
- Women of childbearing potential must use an effective, non-hormonal form of contraception from Screening throughout the Treatment Phase and until 70 days after the last dose of Study treatment
• Acceptable methods include: copper intrauterine device or double barrier methods, including male/female condoms with spermicide and use of contraceptive sponge, cervical cap, or diaphragm
- Male patients must use an effective, non-hormonal form of contraception from Screening throughout the Treatment Phase and until 130 days after last dose of Study treatment
• Acceptable methods include male/female condoms with spermicide, or vasectomy with medical confirmation of surgical success.
- Written informed consent and authorization to use and disclose health information
- Ability to comprehend and comply with the requirements of the Study

**Critères de non-inclusion** : - Two or more prior chemotherapy regimens for advanced disease
- Prior treatment with a taxane in the metastatic setting
- Prior treatment with capecitabine
- Known metastases to the central nervous system
- Other cancer that required therapy within the preceding 5 years other than adequately treated: (a) non-melanoma skin cancer or in situ cancer; or (b) following approval by the Medical Monitor, other cancer that has a very low risk of interfering with the safety or efficacy endpoints of the Study
- Known human immunodeficiency virus infection, unless well controlled. Patients who are on an adequate antiviral regimen with no evidence of active infection are considered well controlled.
- Active hepatitis B or active hepatitis C infection
- Other severe acute or chronic medical or psychiatric condition or laboratory abnormality that may increase the risk associated with Study participation or investigational product 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.
- Presence of neuropathy > Grade 1 per NCI CTCAE version 5.0
- History of hypersensitivity to taxanes; hypersensitivity to the solvent does not preclude patient participation in this Study
- Anticancer treatment, including endocrine therapy, radiotherapy, chemotherapy, biologic therapy, or therapy in an investigational clinical study, <= 14 days prior to the date of Randomization
- Major surgery <= 28 days prior to the date of Randomization; patient must have complete recovery from surgery
- Less than 2 weeks or 5 plasma half-lives (whichever is greater) since last use of a medication or ingestion of an agent, beverage, or food that is a potent inhibitor or inducer of the cytochrome P450 (CYP)3A or CYP2C9 pathways (patients should discontinue taking any regularly-taken medication that is a potent inhibitor or inducer of the CYP3A or CYP2C9 pathways)
- History of hypersensitivity or unexpected reactions to capecitabine, other fluoropyrimidine agents, or any of their ingredients

- Known dihydropyrimidine dehydrogenase (DPD) deficiency. Testing for DPD deficiency must be performed where required by local regulations, using a validated method that is approved by local health authorities.
- Pregnant or breastfeeding
- If, in the opinion of the Investigator, the patient is deemed unwilling or unable to comply with the requirements of the Study
- Treatment with brivudine, sorivudine, or its chemically-related analogs <= 28 days prior to the date of Randomization

## Informations promoteur

**Nom du promoteur** : ODONATE PHARMACEUTICALS

**Type de promoteur** : Industriel

**Adresse** : - 00000 HORS FRANCE

**Coordonnateur** : - *Mail :* - *Tél :*

## Informations centre investigateur n°1

**Nom du centre** : Centre François BACLESSE

**Adresse** : 3 avenue du Général Harris 14000 CAEN

**Investigateur** : Christelle LEVY

**TEC / ARC / IDE** : Sara GROSSI - *Mail :* s.grossi@baclesse.unicancer.fr - *Tél :*

**Ouverture de l'essai** : CLOS

## Liens utiles

**ClinicalTrials** : https://www.clinicaltrials.gov/ct2/show/NCT03326674