EMERALD - RAD1901-308 (dernière mise à jour : 10/01/2020)

http://archimaid.fr/index.php?action=show&id=1045

Informations générales

Titre de l'étude : Elacestrant en monothérapie vs traitement standard pour le traitement des patientes atteintes d'un cancer du sein avancé ER + / HER2- après un traitement inhibiteur CDK4/6 : un essai multicentrique de phase 3 randomisé, ouvert, sous contrôle actif

Traitement : Métastasique ou localement avancé

Type d'étude : Ciblage moléculaire / Innovation thérapeutique

Phase : III **Stade** : Localement avancé à Métastasique **Ligne(s)** : 2, 3

Schéma : This is an international, multicenter, randomized, open-label, active-controlled, event-driven, Phase 3 clinical study comparing the efficacy and safety of elacestrant to the SoC options of fulvestrant or an aromatase inhibitor (AI) in postmenopausal women and in men with advanced or metastatic ER+/HER2- breast cancer, either in subjects with tumors that harbor mutations in the ligand binding domain (LBD) of the estrogen receptor 1 (ESR1) gene (ESR1-mut subjects) or in all subjects regardless of ESR1 status (ESR1-mut and ESR1 wild type [ESR1-WT]) and whose disease has relapsed or progressed on at least one and no more than two prior lines of endocrine therapy (with documented progression), which must have included prior CDK4/6 inhibitor therapy in combination with fulvestrant or an aromatase inhibitor (AI) and for whom hormonal monotherapy with one of the SoC drugs (fulvestrant, anastrozole, letrozole, exemestane) is an appropriate treatment option.

Spécialités / Localisations

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

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

Critères

Critères d'inclusion :
Subjects with proven diagnosis of adenocarcinoma of the breast with evidence of either locally advanced disease not amenable to resection or radiation therapy with curative intent or metastatic disease not amenable to curative therapy.
Subjects must be appropriate candidates for endocrine monotherapy
Subjects must have measurable disease or, nonmeasurable (evaluable) bone-only disease
Female or male subjects age >= 18 years; female subjects must be postmenopausal women and male subjects must not allow pregnancy with their sperm (abstain, do not donate sperm, etc).
Subjects must have ER+/HER2-tumor status
Subjects must have previously received at least one and no more than two lines of endocrine therapy for advanced/metastatic breast cancer and meet additional previous treatment criteria.
Subjects must have received prior treatment with a CDK4/6 inhibitor in combination with either fulvestrant or an aromatase inhibitor (AI).
Subjects may have received no more than one line of chemotherapy in the advanced/metastatic setting.
Subjects must have ctDNA ESR1-mut or ESR1-WT status as determined by central testing before subject is randomized.

Critères de non-inclusion :

Prior treatment with elacestrant, GDC-0810, GDC-0927, GDC-9545, LSZ102, AZD9496, bazedoxifene, or other investigational SERD or investigational ER antagonist.

Prior anticancer or investigational drug treatment within the following windows:
Fulvestrant treatment < 28 days before first dose of study drug
Any endocrine therapy < 14 days before first dose of study drug (with the exception of GnRH agonist therapy in male subjects)
Chemotherapy < 21 days before first dose of study drug
Any investigational anti-cancer drug therapy < 28 days or five half-lives (whichever is shorter) before the first dose of study drug.
Enrollment of subjects whose most recent therapy was an investigational agent should be discussed with the Sponsor
Presence of symptomatic visceral disease as defined in protocol.

Informations promoteur

Nom du promoteur : Radius Pharmaceuticals, Inc.

Type de promoteur : Industriel

Adresse : Radius Pharmaceuticals, Inc. - 00000 HORS FRANCE

Coordonnateur : - *Mail :* - *Tél :*

Informations centre investigateur n°1

Nom du centre : Centre François BACLESSE

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Investigateur : Christelle LEVY

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

Ouverture de l'essai : OUVERT

Liens utiles

Clinical Trials : https://clinicaltrials.gov/ct2/show/study/NCT03778931?term=RAD1901-308&draw=2&rank=1