PROFOUND - (dernière mise à jour : 26/09/2017)

ARCHIMAIDindex.php?action=show&id=39

Informations générales

Titre de l'étude : Etude de phase III randomisée en ouvert évaluant l'efficacité et la sécurité d'emploi de l'olaparib (Lynparza®) en comparaison à l'enzalutamide ou l'acétate d'abiratérone chez les hommes atteints d'un cancer de prostate métastatique résistant à la castration (CPRCm), en échec d'un traitement par un agent hormonal de nouvelle génération et porteurs d'une mutation des gènes impliqués dans la voie de réparation par recombinaison homologue (HRR)

Traitement : Métastasique ou localement avancé

Type d'étude : Ciblage moléculaire / Innovation thérapeutique

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

Schéma : A Phase III, Open Label, Randomized Study to Assess the Efficacy and Safety of Olaparib (Lynparza™) Versus Enzalutamide or Abiraterone Acetate in Men With Metastatic Castration-Resistant Prostate Cancer Who Have Failed Prior Treatment With a New Hormonal Agent and Have Homologous Recombination Repair Gene Mutations (PROfound)

2 arms:
- Experimental: Olaparib
Olaparib is available as a film-coated tablet containing 150 mg or 100 mg of olaparib. Subjects will be administered study treatment orally at a dose of 300 mg twice daily (bid). The planned dose of 300 mg bid will be made up of two x 150 mg tablets twice daily, with 100 mg tablets used to manage dose reductions
- Active Comparator: Enzalutamide OR abiraterone acetate
Enzalutamide:
Enzalutamide is available as capsules containing 40 mg of enzalutamide. Subjects will be administered study treatment orally at a dose of 160 mg once daily.
Abiraterone acetate with prednisone: Abiraterone acetate is available as tablets containing 250 mg of abiraterone acetate. Subjects will be administered study treatment orally at a dose of 1,000 mg once daily in combination with prednisone 5 mg administered twice daily orally.

Spécialités / Localisations

Spécialité n°1 : Organes génitaux masculins

CIM10 - Localisation n°1 : **C61** - Tumeur maligne de la prostate

Critères

Critères d'inclusion : - Histologically confirmed diagnosis of prostate cancer.
- Documented evidence of metastatic castration resistant prostate cancer (mCRPC).
- Subjects must have progressed on prior new hormonal agent (e.g. abiraterone acetate and/or enzalutamide) for the treatment of mCRPC.
- Ongoing therapy with LHRH analog or bilateral orchiectomy.
- Radiographic progression at study entry while on androgen deprivation therapy (or after bilateral orchiectomy).
- Qualifying HRR mutation in tumor tissue.

Critères de non-inclusion : - Any previous treatment with PARP inhibitor, including olaparib.

- Subjects who have any previous treatment with DNA-damaging cytotoxic chemotherapy (prior taxane chemotherapy allowed).
- Other malignancy (including MDS and MGUS) within the last 5 years except: adequately treated non-melanoma skin cancer or other solid tumors curatively treated with no evidence of disease for >=5 years.
- Subjects with known brain metastases.

Informations promoteur

Nom du promoteur : AstraZeneca

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 : Florence JOLY

TEC / ARC / IDE : Astrid LETIEMBRE - *Mail :* a.letiembre@baclesse.unicancer.fr - *Tél :*

Ouverture de l'essai : CLOS

Liens utiles

Clinicaltrials : https://clinicaltrials.gov/ct2/show/NCT02987543?titles=%22PROFOUND%22&cntry1=EU%3AFR&rank=6