MO40653 - IMREAL (dernière mise à jour : 31/03/2020)

https://archimaid.frindex.php?action=show&id=766

Informations générales

Titre de l'étude : Etude de cohortes non-interventionnelle, multicentrique, évaluant l'efficacité et la tolérance d'Atezolizumab en conditions réelles chez des patients traités en pratique clinique de routine

Situation thérapeutique : Métastatique ou localement avancé

Traitement :

Cadre réglementaire : RIPH3

Phase : NA **Stade** : Localement avancé à Métastatique **Ligne(s)** : 2, 3, 4, X

Schéma : This is a non-interventional, multi-country, multi-centre, multiple cohort prospective study, with retrospective collection of prior medical/treatment history data from medical records, designed to assess the real-world outcomes and safety of atezolizumab for indications in the existing label in the real world setting of routine clinical practice.

Spécialités / Localisations

Spécialité n°1 : Organes respiratoires et intrathoraciques

CIM10 - Localisation n°1 : **C34** - Tumeur maligne des bronches et du poumon

Critères

Critères d'inclusion : - Patient must have one of the following confirmed diagnoses for which atezolizumab is locally approved in the SmPC: (1) As monotherapy for the treatment of adult patients with la/mUC after prior platinum-containing chemotherapy or (2) As monotherapy for the treatment of adult patients with la/mNSCLC after prior chemotherapy. Patients with EGFR activating mutations or ALK-positive tumour mutations should also have received targeted therapy before receiving atezolizumab.
- Patient is prescribed atezolizumab therapy for the first time.
- Decision to prescribe atezolizumab must be made and documented prior to inclusion into the study and must follow local clinical practice.
- Initiation of atezolizumab is not more than 28 days before signing informed consent. In countries where enrollment is only allowed after starting treatment, enrollment must be preceded by the administration of the first cycle of atezolizumab.

Critères de non-inclusion : - Treatment with atezolizumab for an indication that is not included in the study cohorts. Cisplatin ineligible participants receiving atezolizumab as first line of therapy for la/mUC will be excluded.
- Concomitant anti-cancer therapy at the time of starting atezolizumab on the index date, as per locally approved Summary of Product Characteristics (SmPC).
- Treatment with atezolizumab as part of a clinical trial or for compassionate use as part of an access or compassionate use program.

Informations promoteur

Nom du promoteur : HOFFMANN-LA ROCHE

Type de promoteur : Industriel

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Informations centre investigateur n°1

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Statut de l'essai : CLOS

Liens utiles

ClinicalTrials : https://clinicaltrials.gov/ct2/show/NCT03782207?term=40653&lead=roche&cntry=FR&rank=1