MS100070_0176 - (dernière mise à jour : 28/01/2020)

http://archimaid.fr/index.php?action=show&id=899

Informations générales

Titre de l'étude : An Open-Label, Multicenter Follow-up Study to Collect Long-term Data on Participants From Multiple Avelumab (MSB0010718C) Clinical Studies

Traitement : Métastasique ou localement avancé

Type d'étude : Hors ciblage moléculaire

Phase : III **Stade** : Localement avancé à Métastasique **Ligne(s)** : 2, 3, 4

Schéma : The main purpose of this study is to monitor the safety and tolerability of avelumab in participants with solid tumors who continue treatment with avelumab under the same treatment regimen as in the parent avelumab study.

Study arm:
Participants entering this roll over study will receive avelumab (MSB0010718C) as a 1-hour intravenous (IV) infusion at 10 milligram per kilogram (mg/kg) once every 2 weeks until progressive disease, according to respective parent studies (EMR100070-001, EMR100070-002, EMR100070-004 and EMR100070-008).

Current primary outcome:
Occurrence of Treatment-related Non-serious Treatment-Emergent Adverse Events (TEAEs), All Serious AEs, Immunerelated AEs and Infusion-related Reactions According to Version of National Cancer Institute Common Technology Criteria for Adverse Events [Time Frame: From enrollment to end of survival follow-up (up to 5 years after the last participant receives the last dose of avelumab)]

Current secondary outcomes:
- Overall Survival (OS) [Time Frame: From baseline up to 5 years]
- Progression Free Survival (PFS) According to Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1) [Time Frame: From baseline up to 5 years]
- Duration of Response (DOR) Assessed From Complete Response (CR) or Partial Response (PR) [Time Frame: From baseline up to 5 years]

Spécialités / Localisations

Spécialité n°1 : Toutes tumeurs solides

CIM10 - Localisation n°1 : **C** - Toutes localisations

Critères

Critères d'inclusion : - Participants under enrollment and treatment in an avelumab clinical study under the sponsorship of EMD Serono Research & Development Institute, Inc. / Merck KGaA, Darmstadt, Germany, Merck Serono Co., Ltd (Japan)
- Participants currently enrolled in an avelumab parent study and are on active treatment with avelumab or in long-term survival follow-up after treatment
- Participants on active treatment must agree to continue to use highly effective contraception (that is, methods with a failure

rate of less than 1% per year) for both male and female participants if the risk of conception exists
- Other protocol defined inclusion criteria could apply.

Critères de non-inclusion : - Participants who are pregnant or breastfeeding
- Participants still on active treatment: Known hypersensitivity to any of the study intervention ingredients
- Participant has been enrolled in the comparator arm of avelumab parent study
- Participant has been withdrawn from avelumab parent study for any reason
- Any other reason that, in the opinion of the Investigator, precludes the participant from participating in the study
- Other protocol defined exclusion criteria could apply.

Informations promoteur

Nom du promoteur : EMD Serono Research & Development Institute, Inc.

Type de promoteur : Industriel

Adresse : - 00000 HORS FRANCE

Coordonnateur : - *Mail :* - *Tél :*

Informations centre investigateur n°1

Nom du centre : Centre Oscar Lambret

Adresse : 3 Rue Frédéric Combemale 59000 LILLE

Investigateur : Professeur Nicolas PENEL

TEC / ARC / IDE : Unité Intégrée de Recherche Clinique - *Mail :* investigation@o-lambret.fr - *Tél :* 03.20.29.59.35

Ouverture de l'essai : CLOS

Liens utiles

ClinicalTrials (anglais) : https://clinicaltrials.gov/ct2/show/record/NCT03815643?term=MS100070_0176&rank=1