POD1UM-202 - PODIUM 202 - INCMGA 0012-202 (dernière mise à jour : 04/12/2019)

http://archimaid.fr/index.php?action=show&id=1001

Informations générales

Titre de l'étude : A Phase 2 Study of INCMGA00012 in Participants With Squamous Carcinoma of the Anal Canal Who Have Progressed Following Platinum-Based Chemotherapy

Traitement : Adjuvant

Type d'étude : Hors ciblage moléculaire

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

Schéma : Ability to comprehend and willingness to sign a written informed consent form.
Confirmed diagnosis of locally advanced or metastatic SCAC.
Must have received (or been intolerant to or ineligible for) at least 1 prior line of platinum-based chemotherapy and received no more than 2 prior systemic treatments.
Must have measurable disease by RECIST v1.1.
Eastern Cooperative Oncology Group performance status of 0 to 1.
If HIV-positive, then all of the following criteria must also be met: CD4+ count ? 300/?L, undetectable viral load, and receiving highly active antiretroviral therapy.

Spécialités / Localisations

Spécialité n°1 : Organes digestifs

CIM10 - Localisation n°1 : **C21** - Tumeur maligne de l'anus et du canal anal

Critères

Critères d'inclusion : Ability to comprehend and willingness to sign a written informed consent form.
Confirmed diagnosis of locally advanced or metastatic SCAC.
Must have received (or been intolerant to or ineligible for) at least 1 prior line of platinum-based chemotherapy and received no more than 2 prior systemic treatments.
Must have measurable disease by RECIST v1.1.
Eastern Cooperative Oncology Group performance status of 0 to 1.
If HIV-positive, then all of the following criteria must also be met: CD4+ count >= 300/?L, undetectable viral load, and receiving highly active antiretroviral therapy.

Critères de non-inclusion : Receipt of anticancer therapy or participation in another interventional clinical study within 21 days before the first administration of study drug; 6 weeks for mitomycin C.
Radiotherapy within 14 days of first dose of study treatment with the following caveats: 28 days for pelvic radiotherapy, 6 months for thoracic region radiotherapy that is > 30 Gy.
Prior treatment with programmed cell death protein 1 (PD-1) or programmed cell death ligand protein 1 (PD-L1)-directed therapy.
Active autoimmune disease requiring systemic immunosuppression.
Known central nervous system (CNS) metastases and/or carcinomatous meningitis.

Known active hepatitis infection.
Active infections requiring systemic therapy.
Is pregnant or breastfeeding or is expecting to conceive or father children within the projected duration of the study, from screening through 6 months after the last dose of study drug.

Informations promoteur

Nom du promoteur : Incyte Corporation

Type de promoteur : Industriel

Adresse : 1801 Augustine Cut-off Wilmington, DE 19803 - 00000 HORS FRANCE

Coordonnateur : - *Mail :* - *Tél :*

Informations centre investigateur n°1

Nom du centre : CHU de Rouen

Adresse : 1 Rue de Germont 76000 ROUEN

Investigateur :

TEC / ARC / IDE : Patricia FOSSE - *Mail :* patricia.fosse@chu-rouen.fr - *Tél :* 02 32 88 86 10 poste 64 462

Ouverture de l'essai : CLOS

Liens utiles

ClinicalTrial : https://clinicaltrials.gov/ct2/show/study/NCT03597295