A Phase 2 Study of INCMGA00012 in Participants With Squamous Carcinoma of the Anal Canal Who Have Progressed Following Platinum-Based Chemotherapy

Published: 22-10-2018
Last updated: 12-04-2024

To assess efficacy of INCMGA00012 in terms of the ORR in participants with locally advanced or metastatic SCAC who have progressed after platinum-based chemotherapy.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Anal and rectal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON48162

Source
ToetsingOnline

Brief title
INCMGA00012 progressive Squamous Carcinoma Anal Canal phase 2 Study

Condition

- Anal and rectal conditions NEC
- Metastases

Synonym
Squamous Carcinoma Anal canal (SCAC) - Anal Cancer

Research involving
Human

Sponsors and support

Primary sponsor: Incyte Biosciences Benelux B.V.

Source(s) of monetary or material Support: Biotechnologisch bedrijf: Incyte Corporation

Intervention

Keyword: Anal Canal, Immunotherapy, Progressive, Squamous Carcinoma

Outcome measures

Primary outcome

Overall Response Rate, defined as the percentage of participants having a CR (complete response) or PR (partial response), according to RECIST v1.1 as determined by ICR (Independent Central Radiographic Review)

Secondary outcome

- DOR (duration of response), defined as the time from an initial objective response (CR or PR) according to RECIST v1.1 until disease progression as determined by ICR (Independent Central Radiographic Review) or death due to any cause.

- DCR (disease control rate), defined as the number of participants maintaining either an ORR or stable disease.

- PFS (progression free survival), defined as the time from the first dose of study treatment until disease progression by ICR or death due to any cause.

- OS (Overal survival), defined as the time from the start of therapy until death due to any cause.

- Safety, determined by the number of participants; the frequency, duration, and severity of AEs; laboratory tests; vital signs; and ECGs.

- Population PK (Pharmacokinetics), including Cmax, Tmax, Cmin, and AUC0-t, will be summarized.

Exploratory:

-Blood and/or tumor analytes, immune cell profile, viral profiles, and other relevant markers will be evaluated with respect to safety and efficacy outcome measures.

-Immunogenicity, defined as the occurrence of specific ADAs (Anti-drug Antibodies) to INCMGA00012.

-Efficacy parameters will be evaluated according to iRECIST as assessed by the investigator.

-Evaluations may include PRO (patient-reported outcome) assessments scheduled to align with tumor response.

-HIV viral load and CD4+ counts will be monitored in participants who are known to be HIV-positive.

Study description

Background summary

Squamous cell carcinoma of the anal canal (SCAC) accounts for almost 3% of digestive system cancers and is increasing in frequency due to its association with HPV and HIV infection. Although most patients have localized disease, systemic metastases will develop in approximately 25% of patients, and 5-year survival is poor in these individuals. Chemotherapy with platinum-based regimens is an accepted standard of care; however, responses are not durable, and progression-free and overall survival after these treatments is measured only in months. There are no accepted salvage treatments for patients who progress after first-line chemotherapy
Immunotherapy, like PD-1 inhibitor MGA00012 may be a promising new approach to the treatment of metastatic SCAC. This is investigated in this study.

Study objective

To assess efficacy of INCMGA00012 in terms of the ORR in participants with locally advanced or metastatic SCAC who have progressed after platinum-based

chemotherapy.

Study design

Open-label, single-group, multicenter, Phase 2 study

Intervention

All participants will receive INCMGA00012 at the recommended Phase 2 dose of 500 mg IV Q4W. Treatment will be administered by IV infusion over 60 minutes on Day 1 of each 28-day cycle.

In order to properly determine the patient's response to the therapy, regularly blood is taken, CT Scan or MRI is made, urine is collected and asked to participants to complete quality of live questionnaires on a device.

HIV positive patients are asked if they want to participate in an optional study. If a patient consents to participate, the amount of blood taken per study visit differs, this is either 20 ml less or 60 ml more per study visit. In total about 805 ml blood would be taken from these patients.

Study burden and risks

This therapy might give side effects, like fatigue and vomiting, nausea, pyrexia (fever), anemia, dehydration. All possible reported AEs seen so far have been described in the Investigator's Brochure and additional (SUSAR) reports. In addition the tests to be done might result in some risks, like drawing blood, taking ECG, MRI, CT scan, biopt.

The study medicine may prove beneficial in this disease or relieve symptoms, but this is not certain. The information obtained thanks to this study may contribute to a better knowledge of the use of this medicinal product or to the development of a new medicinal product for the treatment of Squamous Carcinoma of the Anal Canal in future patients.

Contacts

Public
Incyte Biosciences Benelux B.V.

Paasheuvelweg 25
Amsterdam 1105 BP
NL
Scientific

Incyte Biosciences Benelux B.V.

Paasheuvelweg 25
Amsterdam 1105 BP
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Male and female participants at least 18 years of age with locally advanced or metastatic SCAC who have progressed after platinum-based chemotherapy.
According to Protocol version 4, dated 08-Jul-2019 an update of the criteria:
a Prior 2 lines of systemic therapy for metastatic disease are permitted.
b Participants who are ineligible for platinum must have received at least 1 prior line of systemic therapy.
c. Participants receiving platinum-based radiosensitizing chemotherapy are eligible if relapse occurs within 6 months from completion of treatment.

Exclusion criteria

Toxicity of prior therapy that has not recovered to <= Grade 1 or baseline (with the exception of any grade of alopecia and anemia not requiring transfusion support).

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	2
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	unknown
Generic name:	unknown

Ethics review

Approved WMO Date:	22-10-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-07-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-08-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	14-08-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-09-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-10-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-01-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-01-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2018-002070-51-NL
ClinicalTrials.gov	NCT03597295
CCMO	NL67586.068.18