A Phase I Study to Assess Biodistribution of 89Zr-CB307 in PSMA+ and PSMA-Tumour Lesions

Published: 22-08-2022
Last updated: 07-04-2024

To assess the safety of 89ZrCB307To assess 89Zr-CB307 uptake by PET scan

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON51775

Source
ToetsingOnline

Brief title
CB307 Radio-labeled sub-study

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
advanced tumours, Metastatic tumours

Research involving
Human

Sponsors and support

Primary sponsor: Cresendo Biologics Ltd
Source(s) of monetary or material Support: Cresendo Biologics Ltd

Intervention

Keyword: Advanced and Metastatis Solid Tumours, PSMA, Radio-labeled, T-cell enhancer

Outcome measures

Primary outcome

•To assess the safety of 89Zr-CB307: Incidence (frequency and severity) of adverse events occurring following administration of 89Zr-CB307 assessed by CTCAE ver 5.0;

•To assess 89Zr-CB307 uptake by PET scan: SUVpeak - maximum standardised uptake value; SUVmean - mean standardised uptake value; Percentage of Injected Dose per Gram of Tissue (%ID/g) in the tumour.

Secondary outcome

During the conduct of the sub-study, multiple PET scans will be performed and safety assessments for the evaluation of the safety profile will be done. In addition, safety laboratory parameters and electrocardiogram (ECG) data will be evaluated using data after completion of the sub-study and prior to commencing C1D1 of the main study. Any AEs or SAEs that occur during the screening period or the sub-study will be followed up until resolution. If the AE is not resolved at the time of completion of the sub-study or by the required follow-up period of the sub-study, these data will be reported in the main study.

Study description

Background summary

CB307 is a trispecific Humabody® targeting CD137; PSMA; and human serum albumin (HSA) undergoing Phase 1 assessment in patients with PSMA+ solid tumours. This sub-study will assess the biodistribution of radiolabelled CB307 in patients with advanced and/or metastatic solid tumours that are PSMA+.

Study objective

To assess the safety of 89ZrCB307
To assess 89Zr-CB307 uptake by PET scan

Study design

Following administration of 89Zr-CB307, enrolled patients will undergo a number of PET scans where uptake of the radiolabelled drug will be assessed and a post-treatment tumour biopsy (for assessment of PSMA expression) will be taken, if medically feasible, after the last PET scan.

The sub-study consists of 2 parts: an Optimisation Phase (Part A) and an Expansion Phase (Part B).

In Part A, following administration of 89Zr-CB307, patients will undergo PET scans (a maximum of 3 post-tracer PET scans). The timing of the scans and post-dose tumour biopsy and level of CB307 cold dose to be administered will be determined by the Optimisation Review Committee (ORC)

In Part B (Expansion Phase), 89Zr-CB307 PET scanning will be performed up to a maximum of 2 times based on the optimal dosing and timing determined in Part A by the ORC

Intervention

Radio-labeled CB307

Study burden and risks

There is no clinical data available for CB307 to date. Preclinical studies suggest that activation CD137-positive T cells is observed with CB307 in the presence of PSMA-expressing tumours. Hepatotoxicity observed in urelumab may be mitigated, as CB307 does not contain an Fc region and does not induce nonspecific macrophage activation. In addition, the starting dose of the first in human study is selected carefully based on the toxicology and pharmacology studies. Based on the preliminary result of PRS343, a CD137 targeting bispecific agent and the results of AMG212 and HPN424, both PSMA-and CD3 targeting bispecific molecules, CB307 may demonstrate efficacy in a clinical trial with an acceptable safety profile and it is considered that the potential

benefits outweigh the potential risks

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Is capable of understanding the written informed consent form (ICF), provides signed and witness informed consent and agrees to comply with protocol requirements
2. Is aged at least 18 years at the time of signing the ICF
3. Has a documented, histologically-confirmed diagnosis of advanced or metastatic solid tumours

See protocol page 26 for the full list of inclusion criteria)
Note: Subject must qualify for the main study and must have met the relevant

inclusion and exclusion criteria and signed the ICF for the main study (see also section J)

Exclusion criteria

1. Has evidence of autoimmune or significant, uncontrolled concomitant diseases that could affect compliance with the protocol or interpretation of the results
2. Has discontinued from anti-cytotoxic lymphocyte-associated protein 4, anti-programmed cell death protein 1, or anti-programmed cell death ligand 1 antibody because of intolerable toxicity according to the investigator*s assessment.
3. Has brain metastasis, including leptomeningeal metastasis or a primary brain tumour.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-07-2023
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	CB307
Generic name:	-

Ethics review

Approved WMO Date:	22-08-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-10-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-12-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-02-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-02-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-05-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2021-006256-13-NL
CCMO	NL82094.042.22