A Phase 1b, Multicenter, Open-Label Study to Determine the Safety, Tolerability, Pharmacokinetics, and Preliminary Efficacy of ABBV-368 plus Tilsotolimod and Other Therapy Combinations in Subjects with Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma

Published: 16-03-2020
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To assess safety, tolerability, and PK of ABBV-368 plus tilsotolimod; ABBV-368 plus tilsotolimod and nab-paclitaxel; and ABBV-368 plus tilsotolimod, nab-paclitaxel, and Budigalimab in subjects with R/M HNSCC.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Plasma cell neoplasms
Study type	Interventional

Summary

ID

NL-OMON49382

Source
ToetsingOnline

Brief title
M19-894

Condition

- Plasma cell neoplasms

Synonym
head and neck cancer, Head and neck squamous cell carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: AbbVie B.V.
Source(s) of monetary or material Support: AbbVie

Intervention

Keyword: head and neck squamous cell carcinoma (HNSCC)

Outcome measures

Primary outcome

- Safety evaluations include AE monitoring, physical examinations, vital sign measurements, and clinical laboratory testing (hematology, chemistry, and urinalysis) as measures of safety and tolerability for the entire study duration.

- Blood samples to assess serum concentrations of ABBV-368 and budigalimab and plasma concentrations of tilsotolimod will be obtained at the visits indicated in the Activity Schedule

The following PK parameters will be determined for ABBV-368, tilsotolimod and budigalimab (if applicable) after infusion between Cycle 1 to Cycle 3 using noncompartmental methods, as applicable based on data availability of the individual compounds:

• maximum observed serum/plasma concentration (Cmax)

• time to Cmax (Tmax)

• area under the serum/plasma concentration versus time curve from time 0 to

the time of the last measurable concentration (AUC*)

• terminal-phase elimination rate constant (β); and terminal half-life (t1/2)

• additional parameters may be calculated if useful in the interpretation of

the PK data. The immunogenicity of tilsotolimod, ABBV-368, and budigalimab will

be assessed to aid in the interpretation of PK data.

Secondary outcome

Efficacy endpoints based on RECIST, v1.1:

- Objective response rate (ORR): the proportion of subjects with CR or PR as a

confirmed response

- Clinical benefit rate (CBR): the proportion of subjects with a confirmed CR,

confirmed PR, or SD

- Time to response (TTR): among subjects who responded, TTR is the time from

date of first study drug exposure to the first instance of a CR or PR as a

confirmed response, whichever occurs first

- Progression free survival (PFS): the time from date of first study drug

exposure to disease progression or death, whichever occurs first

- Duration of response (DOR): the time from the subject's initial response (CR

or PR as a confirmed response) to disease progression or death, whichever

occurs first

Study description

Background summary

Head and neck squamous cell carcinoma (HNSCC) is one of the most common type of cancers worldwide. People over age 50 are most vulnerable, particularly those

who use tobacco. HNSCC can occur in areas including the mouth, throat, or voice box. The cancer can cause patches or open sores (ulcers) in the mouth/throat, bleeding/pain, sore throat, pain or difficulty when swallowing, hoarse voice, difficulty breathing or enlarged lymph nodes.

Study objective

To assess safety, tolerability, and PK of ABBV-368 plus tilsotolimod; ABBV-368 plus tilsotolimod and nab-paclitaxel; and ABBV-368 plus tilsotolimod, nab-paclitaxel, and Budigalimab in subjects with R/M HNSCC.

Study design

Non-Randomized, open-label, sequential assignment.

Intervention

There are 3 arms to the study - Arm 1, Arm 2, and Arm 3. Participants will be placed in one of the following arms:
• Arm 1: ABBV-368 + tilsotolimod
• Arm 2: ABBV-368 + tilsotolimod + nab-paclitaxel
• Arm 3: ABBV-368 + tilsotolimod + nab-paclitaxel + ABBV-181

Study burden and risks

The effect of treatment on the disease will be checked by performing diagnostic imaging, blood tests, and tissue collection (some optional). Safety evaluations will occur throughout the study and will include blood and urine tests, electrocardiogram (ECG), and physical exams.

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

- At least 18 years old and weigh at least 35 kg
- Eastern Cooperative Oncology Group performance status of 0 or 1 and a life expectancy of >= 3 months
- Have >= 1 lesion accessible for intratumoral injection and lesion(s) must be >= 2 cm in longest diameter.
- Histologically or cytologically confirmed R/M HNSCC (of the following 4 subsites: oral cavity, oropharynx, larynx, and hypopharynx) who previously progressed either during or after <= 3 prior treatment regimens administered in the recurrent or metastatic setting. Must have received 1 immunotherapy regimen which included a PD-(L)1 inhibitor.
Must have received platinum-based therapy (either in the definitive or advanced, recurrent/metastatic setting), or be considered ineligible for platinum-based therapy by the investigator.

Exclusion criteria

- No uncontrolled metastases to the central nervous system (CNS). Subjects with brain metastases are eligible provided that evidence of clinical and radiographic stable disease for at least 4 weeks after definitive therapy is given and subjects have not used prohibited levels of steroids for at least 4 weeks prior to first dose of the study.
- Must not have received prior treatment with OX40 or TLR agonists (excluding topical agents)

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):	01-06-2021
Enrollment:	2
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ABBV-181
Generic name:	Niet van toepassing
Product type:	Medicine
Brand name:	ABBV-368
Generic name:	Niet van toepassing
Product type:	Medicine
Brand name:	Nab-Paclitaxel
Generic name:	Abraxane
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Tilsotolimod
Generic name:	Niet van toepassing

Ethics review

Approved WMO

Date:	16-03-2020

Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-05-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-12-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	03-12-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-01-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-03-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	03-04-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	27-05-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	27-08-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	28-12-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-04-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2019-003167-22-NL
ClinicalTrials.gov	NCT04196283
CCMO	NL72205.056.20

Study results

Results posted:	05-10-2023

Summary results
Trial ended prematurely

First publication
27-09-2023