A Phase 1 First-in-Human Study with ABBV-155 Alone and in Combination with Taxane Therapy in Adults with Relapsed and/or Refractory Tumors

Published: 30-07-2020
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This study has been transitioned to CTIS with ID 2024-513625-23-00 check the CTIS register for the current data. Primary objectives:•To determine the maximum-tolerated dose (MTD) and recommended Phase 2 dose (RPTD) of ABBV-155 administered as...

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

Summary

ID

NL-OMON55246

Source
ToetsingOnline

Brief title
M16-573

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
(non) small cell lunger cancer + breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: AbbVie Deutschland GmbH & Co. KG
Source(s) of monetary or material Support: AbbVie

Intervention

Keyword: Breast Cancer, First-in-Human, NSCLC, SCLC

Outcome measures

Primary outcome

• Dose limiting toxicity (DLT); defines Maximum Tolerated Dose (MTD) and

Recommended Phase Two Dose (RPTD)

• Overall Response Rate (ORR)

Secondary outcome

• Duration of Response (DOR)

• Complete Response (CR)

• Progression Free Survival (PFS)

• Overall Survival (OS)

• Pharmacokinetics (PK)

• QT prolongation (Parts 1a, 2a)

Study description

Background summary

Cancer is a condition where cells in a specific part of the body grow and reproduce uncontrollably. This study focuses on solid tumors (solid cancers). The study drug ABBV-155 is being investigated for the treatment of solid cancers. The purpose of this study is to see how safe and effective ABBV-155 is, when given alone, and in combination with paclitaxel or docetaxel, to treat solid tumors.

Study objective

This study has been transitioned to CTIS with ID 2024-513625-23-00 check the CTIS register for the current data.

Primary objectives:
•To determine the maximum-tolerated dose (MTD) and recommended Phase 2 dose (RPTD) of ABBV-155 administered as monotherapy (Part 1a)
•To determine MTD and RPTD of ABBV-155 administered in combination with paclitaxel or docetaxel (Part 1b)
•To evaluate the overall response rate (ORR) of ABBV-155 among subjects with relapsed or refractory (R/R) SCLC (Part 2a)
•To evaluate the ORR of ABBV-155 in combination with paclitaxel in subjects with R/R breast cancer and in combination with docetaxel in subjects with R/R NSCLC (Part 2b).

Secondary objectives:
•To evaluate the safety and tolerability of ABBV-155 administered alone and in combination with paclitaxel or docetaxel
•To evaluate the pharmacokinetic (PK) of ABBV-155 administered alone and in combination with paclitaxel or docetaxel
•To evaluate the efficacy of ABBV-155 alone and in combination with paclitaxel or docetaxel
•To evaluate the effect of systemic ABBV-155 administration on QT prolongation (Parts 1a, 2a)

Study design

Non-randomized, Open label, Parallel group assignment.

Intervention

The study consists of 2 parts - Dose Escalation (Part 1) and Dose Expansion (Part 2). In the dose escalation part (Part 1), participants will receive escalating doses of intravenous ABBV-155 monotherapy (Part 1a) or ABBV-155 in combination with paclitaxel or docetaxel (Part 1b). In the dose expansion part (Part 2), participants will either receive ABBV-155 as monotherapy or as a combination therapy with a taxane (paclitaxel or docetaxel). ABBV-155 monotherapy cohort will enroll participants with relapsed or refractory (R/R) small cell lung cancer (SCLC) (Part 2a). ABBV-155 with a taxane (paclitaxel or docetaxel) combination cohort will enroll participants with R/R non-small cell lung cancer (NSCLC) and breast cancer (Part 2b).

Study burden and risks

There may be a higher treatment burden for participants in this trial compared

to their standard of care. Participants will attend regular visits during the study at a hospital or clinic. The effect of the treatment will be checked by medical assessments, blood tests, checking for side effects, and completing questionnaires.

Contacts

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AbbVie Deutschland GmbH & Co. KG

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Scientific
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DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Has a histologic or cytologic diagnosis of a malignant solid tumor.
• Subjects enrolled in Part 2a (monotherapy, dose expansion) must have SCLC diagnosis.
• Subjects enrolled to Part 2b (combination therapy, dose expansion) must have either NSCLC or HR-positive/HER2-negative breast cancer. For Part 2, sponsor may elect (at its discretion) to prospectively screen for subjects whose tumor

express B7H3 based on central IHC assessment of fresh or archival tumor tissue.
• Measurable disease defined by Response Evaluation Criteria in Solid Tumors (RECIST) criteria.
• An Eastern Cooperative Oncology Group (ECOG)performance status less than or equal to 2.
• Failure of at least 1 prior systemic chemotherapy including all available standard therapies for subjects in the dose-escalation phase (Parts 1a and 1b).
• All subjects with breast cancer for subjects in the dose expansion phase (Part 2b only) must have the following:
- locally advanced or metastatic HR-positive/HER2-negative breast cancer after failing cyclindependent kinase (CDK)4/6 inhibitor-based therapy.
- HR-positivity and HER-2-negativity should be confirmed based on American Society of Clinical Oncology (ASCO)/College of American Pathologists (CAP) criteria.
• All subjects with non-small cell lung cancer (NSCLC) for subjects in the dose-expansion phase (Part 2b only) must have R/R NSCLC after at least 1 line of therapy.
• All subjects with SCLC in the dose-expansion phase (Part 2a only) must have R/R SCLC from at least 1 line of therapy which includes a platinum-based therapy with or without an anti-PD-L1/PD-1 therapy.
• All subjects with either breast cancer or NSCLC must have the following if exposed to prior taxane-based therapy:
-no history of taxane allergy (Parts 1b and 2b only)
-disease that has relapsed or progressed at least 2 months after initiation of the most recent taxane-based therapy.
• Available tumor tissue suitable for immunohistochemistry testing.
• Adequate kidney, liver, and hematologic laboratory values as described in the protocol.

Exclusion criteria

• No untreated brain or meningeal metastases (i.e., subjects with history of metastases are eligible provided they do not require ongoing steroid treatment and have shown clinical and radiographic stability for at least 28 days after definitive therapy.
• Grade 2 or higher peripheral neuropathy (only applies to subjects who would receive taxane therapy).
• Unresolved Grade 2 or higher toxicities related to previous anticancer therapy except alopecia.
• Known active infection of hepatitis B, hepatitis C, or human immunodeficiency virus with exceptions as described in the protocol.
• Recent history (within 6 months) of congestive heart failure (defined in the protocol), ischemic cardiovascular event, cardiac arrhythmia requiring pharmacological or surgical intervention, pericardial effusion, or pericarditis.
• Any history of hypersensitivity to any ingredients of ABBV-155 will be

excluded. For combination therapy only (Parts 1b and 2b), history of serious allergic reaction to any taxane or any ingredients used in taxane formulation.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-03-2021
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Docetaxel
Generic name:	Docetaxel
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Mirzotamab Clezutoclax
Generic name:	ABBV-155
Product type:	Medicine
Brand name:	Paclitaxel
Generic name:	Paclitaxel
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	30-07-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-09-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-10-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-12-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-12-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-03-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-03-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-03-2021
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	02-04-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-04-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-08-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-09-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-09-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	22-12-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	31-12-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	

Date:	16-02-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-09-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-03-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-08-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	03-05-2024
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-05-2024
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
EU-CTR	CTIS2024-513625-23-00
EudraCT	EUCTR2020-002495-12-NL
ClinicalTrials.gov	NCT03595059
CCMO	NL74586.056.20