A Multicenter, Single Arm, Open-label Study to Investigate the Efficacy and Safety of Ravagalimab (ABBV-323) in Subjects with Moderate to Severe Ulcerative Colitis Who Failed Prior Therapy

Published: 11-10-2018
Last updated: 25-03-2025

The main objective of Study M15-722 is to characterize the efficacy, safety, and tolerability of ravagalimab (ABBV-323) as induction treatment in subjects with moderately to severely active UC.

Ethical review	Approved WMO
Status	Completed
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON49261

Source
ToetsingOnline

Brief title
M15-722

Condition

- Gastrointestinal inflammatory conditions
- Autoimmune disorders

Synonym
Chronic colon inflammation, IBD

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Drug Therapy (DT), Immunology (IM), Ulcerative Colitis

Outcome measures

Primary outcome

The primary endpoint for Study M15-722 is the proportion of subjects with

endoscopic improvement (Mayo endoscopic subscore of 0 or 1) at Week 8.

Secondary outcome

Secondary Endpoints for Induction Period (Weeks 0 to 12)

- Proportion of subjects with clinical remission per Adapted Mayo score at Week

8

- Proportion of subjects with clinical response per Adapted Mayo score at Week

8

- Proportion of subjects with clinical response per Partial Adapted Mayo score

over time

- Proportion of subjects with clinical remission per Full Mayo score at Week 8

in subjects with a Full Mayo score of 6 to 12 at Baseline

- Proportion of subjects with endoscopic remission at Week 8

Study description

Background summary

Ulcerative colitis (UC) is a chronic, relapsing inflammatory disease of the large intestine characterized by inflammation and ulceration of mainly the mucosal and, occasionally, submucosal intestinal layers. The hallmark clinical symptoms of UC include bloody diarrhea associated with rectal urgency and tenesmus. The most severe intestinal manifestations of UC are toxic megacolon and perforation.

Patients with UC are at an increased risk for colon cancer, and the risk increases with the duration of disease as well as extent of colon affected by the disease.

The aim of medical treatment in UC is to control inflammation and reduce symptoms. Available pharmaceutical therapies are limited, do not always completely abate the inflammatory process, and may have significant adverse effects.

Ravagalimab (ABBV-323) is a monoclonal antibody that works by antagonizing CD40. CD40 is a tumor necrosis factor (TNF) receptor family member that plays an important role in lymphocyte activation and antigen presenting cell (APC) function.

Study objective

The main objective of Study M15-722 is to characterize the efficacy, safety, and tolerability of ravagalimab (ABBV-323) as induction treatment in subjects with moderately to severely active UC.

Study design

Study M15-722 is a Phase 2a, multicenter, single arm, open-label studydesigned to evaluate the efficacy and safety of intravenous and subcutaneous administration of ravagalimab (ABBV-323) as induction therapy for 12 weeks in subjects with moderately to severely active UC.
At the end of week 12, if subjects have a clinical response, they may continue to receive ravagalimab (ABBV-323) in the 92-week maintenance portion of the study.

Intervention

Participants administered with ravagalimab (ABBV-323) dose A IV and ravagalimab (ABBV-323) dose B for 12 Weeks. Participants who achieve clinical response may enter the maintenance period in which participants are administered with ravagalimab (ABBV-323) dose B.

Study burden and risks

There will be higher burden for subjects participating in this study compared to their standard of care. Subjects will be visiting the clinic more frequently. During these visits study procedures will be performed including blood sampling and endoscopies. Subjects will be tested for TB, Hepatitis C/Hepatitis B and HIV. Women of childbearing potential must practice a method of birth control during the study through at least 84 days after the last dose of study drug and will be tested for pregnancy.
Ravagalimab (ABBV-323) has not been studied before in subjects with ulcerative colitis. Studies in healthy volunteers showed that ravagalimab (ABBV-323) was well tolerated and that there were no identified safety concerns. Side effects for drugs that work in a similar way as ravagalimab (ABBV-323) are: serious infections such as hepatitis, pneumonia, cellulitis, urinary tract infection, diverticulitis and shingles; opportunistic infections such as tuberculosis, fungal and viral infections; lab test abnormalities such as elevated liver function tests.

Contacts

Public
AbbVie B.V.

Wegalaan 9
Hoofddorp 2132 JD
NL
Scientific
AbbVie B.V.

Wegalaan 9
Hoofddorp 2132 JD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

· Subjects must voluntarily sign and date an informed consent, approved by an independent ethics committee (IEC)/institutional review board (IRB), prior to the initiation of any screening or study-specific procedures.
· Adult male or female, between 18 and 75 years of age, inclusive, at time of the Baseline visit.
· Diagnosis of UC for at least 3 months prior to Baseline. Appropriate documentation of biopsy results consistent with the diagnosis of UC or in the assessment of the Investigator, must be available.
· Subject meets the following disease activity criteria: Active UC with an Adapted Mayo score of 5 to 9 points and endoscopic subscore of 2 to 3 (confirmed by central review).
· History of inadequate response, loss of response, or intolerance to one or more of the approved biologic therapies: infliximab, adalimumab, golimumab, vedolizumab, and/or tofacitinib (Note: If tofacitinib was received in a clinical trial, subject must have received open-label drug).
- Laboratory values meeting the following criteria:
Serum aspartate transaminase (AST) and alanine transaminase (ALT) <= 2 × upper limit of
normal (ULN);Total white blood cell (WBC) count >= 3.0 × 109 /L;

Exclusion criteria

- Subject must not have an active, chronic, or recurrent infection that based on the Investigator's clinical assessment makes the subject an unsuitable candidate for the study
- Subject must not have any malignancy except for successfully treated non metastatic cutaneous squamous cell or basal cell carcinoma or localized carcinoma in situ of the cervix.
- Subject must not have history of dysplasia of the gastrointestinal tract or evidence of dysplasia in any biopsy performed during the Screening endoscopy

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	05-11-2020
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ravagalimab
Generic name:	Ravagalimab

Ethics review

Approved WMO Date:	11-10-2018
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	23-11-2018
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-12-2018
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	15-07-2019

Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	06-08-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	25-09-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	13-11-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	13-01-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	19-06-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	28-07-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	27-01-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	01-02-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	EUCTR2018-000930-37-NL
CCMO	NL67056.028.18

Study results

Date completed: 14-09-2021

Results posted: 14-02-2023

Summary results
Trial ended prematurely

URL result
URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

Internal documents
File