An Extension Study for Treatment of Moderately to Severely Active Ulcerative Colitis

08/08/2025 07:47:19

Main Information

Primary registry identifying number
LBCTR2020043428

Protocol number
APD334-303

MOH registration number
2020/2/33126

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency
04/05/2015

Primary sponsor
Arena Pharmaceuticals Inc.

Primary sponsor: Country of origin
United States of America

Date of registration in primary registry
02/12/2020

Date of registration in national regulatory agency
04/05/2015

Public title
An Extension Study for Treatment of Moderately to Severely Active Ulcerative Colitis

Acronym

Scientific title
An Open-Label Extension Study of Etrasimod in Subjects With Moderately to Severely Active Ulcerative Colitis

Acronym

Brief summary of the study: English
The purpose of this open-label extension (OLE) study is to evaluate the safety and efficacy of etrasimod in participants with moderately to severely active ulcerative colitis (UC) who previously received double-blinded treatment (either etrasimod 2 mg per day or placebo) during participation in one of two Phase 3 double-blinded, placebo-controlled studies (either Study APD334-301 or APD334-302).

Brief summary of the study: Arabic
الغرض من هذه الدراسة التمديدية هو تقييم سلامة وفعالية etrasimod في المشاركين الذين يعانون من التهاب القولون التقرحي النشيط بشكل معتدل إلى شديد (UC) و الذين كانوا قد تلقوا سابقًا علاجًا APD334-302 أو APD334-301 أثناء المشاركة في واحدة من الدراستين (Etrasimod 2mg or placebo)

Health conditions/problem studied: Specify
Ulcerative Colitis (UC)

Interventions: Specify
Drug: Etrasimod (APD334) 2mg tablet by mouth, once daily up to approximately 5 years or until marketing authorization is obtained in the participant's country, whichever comes first

Key inclusion and exclusion criteria: Inclusion criteria
Subjects are eligible to enroll into this study if they fulfill ALL of the following:
1. Must have met the eligibility criteria and have been enrolled in one of the two parent

studies (APD334-301 or APD334-302) and also meet the following additional criteria:
a. Subjects previously enrolled in Study APD334-301 must have either:
I. Completed the Week 12 visit and have been assessed to have active UC that had deteriorated from baseline and meet one of the following criteria:
• Absolute RB ≥ 2 on 2-consecutive days, and confirmation of ES ≥ 2 at or after the Week 12 assessment
• Absolute RB + SF ≥ 4 on 2-consecutive days, and confirmation of ES ≥ 2 at or after the Week 12 assessment
• Absolute RB ≥ 2 or RB + SF ≥ 4 (in any order) on 2-consecutive days, and confirmation of ES ≥ 2 at or after the Week 12 assessment
or
II. Completed the Week 52 visit
Note: An endoscopic evaluation is required, however a proctosigmoidoscopy does not need to be repeated if performed within the last 4 weeks
b. Subjects previously enrolled in APD334-302 must have completed the Week 12 visit
2. Eligible women of childbearing potential must fulfill the following:
a. Have a negative urine beta human chorionic gonadotropin (β-hCG) pregnancy test
b. Not breastfeeding
3. Both men and women subjects agree to use a highly effective method of birth control throughout the entire study period, from informed consent through the adverse event reporting period (30 days after the last dose of study treatment), if the possibility of conception exists. Eligible men and women subjects must also agree not to participate in a conception process (ie, actively attempt to become pregnant or to impregnate, sperm donation, in vitro fertilization) during the study and for 30 days after the last dose of study treatment. Highly effective birth control methods include the following
• Oral, implantable, or injectable contraceptives (starting ≥ 60 days before dosing) in combination with a diaphragm with vaginal spermicide, cervical cap with vaginal spermicide, or male condom; hormonal contraceptives (subjects should be consistently taking the hormonal contraceptive for at least 3 months [90 days] prior to the Eligibility assessment)
• Standard intrauterine device (IUD; eg, Copper T 380A IUD), intrauterine system (IUS; eg, LNg 20 IUS - progesterone IUD), progesterone implant, or tubal sterilization (≥ 180 days after surgery)
• Vasectomized male subjects using a condom, partner using diaphragm with spermicide, cervical cap with spermicide, estrogen and progesterone oral contraceptives (“the pill”), estrogen and progesterone transdermal patch, vaginal ring, or progesterone injection
• Complete sexual abstinence defined as refraining from heterosexual intercourse for the entire period of risk associated with study treatments. The reliability of sexual abstinence needs to be evaluated in relation to the duration of the clinical trial and the preferred and usual lifestyle of the subject. Periodic abstinence (calendar, symptothermal, post-ovulation methods) is not acceptable
Note: Women who are surgically sterile or postmenopausal (defined as: 12 consecutive months with no menses without an alternative medical cause) are not considered to be of childbearing potential. If of childbearing potential, female partners of participating male subjects should agree to utilize a highly effective method of contraception for the duration of study participation.
4. Ability to provide written informed consent or assent (parent or legal guardian must provide consent for a subject < 18 years of age or as required per local regulations who has assented to participate in the study) and to be compliant with the schedule of protocol assessments

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

16

Key inclusion and exclusion criteria: Age maximum

80

Key inclusion and exclusion criteria: Exclusion criteria

Subjects who meet ANY of the following exclusion criteria will NOT be eligible for enrollment into the study:
1. If the Investigator considers the subject to be unsuitable for any reason to participate in the OLE study
Exclusions related to general health
2. Experienced an adverse event that led to discontinuation from parent etrasimod study
3. Day 1 pre-dose sitting vital sign assessment: heart rate < 50 bpm and systolic BP < 90 mm Hg
4. Day 1 pre-dose 12-lead electrocardiogram (ECG) in the supine position showing a second or third-degree AV block, periods of asystole > 3 seconds, PR interval > 200 ms, or QTcF ≥ 450 ms (males) or QTcF ≥ 470 ms (females)
5. Subjects requiring colectomy during the parent study
6. Subjects requiring treatment with prohibited medications as defined in the parent study

Exclusions related to laboratory results
7. Laboratory values that meet study treatment discontinuation rules
Note: In the case of any abnormal laboratory results, laboratory tests may be repeated once and if these results are within normal range, the subject is eligible for enrollment.

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Therapy

Trial scope: Specify scope

N/A

Study design: Allocation

N/A: Single arm study

Study design: Masking

Open (masking not used)

Study design: Control

N/A

Study phase

3

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Single

Study design: Specify assignment

N/A

IMP has market authorization

No

IMP has market authorization: Specify

Name of IMP

APD334 (Etrasimod)

Year of authorization

Month of authorization

Type of IMP

Others

Pharmaceutical class

Highly selective sphingosine 1-phosphate (S1P) receptor modulator

Therapeutic indication

Ulcerative Colitis

Therapeutic benefit

Clinical remission of moderately to severely active ulcerative colitis

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

Time perspective: Specify perspective

N/A

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

Samples with DNA**

Biospecimen description

Both Samples with DNA and Samples without DNA will be processed

Target sample size

20

Actual enrollment target size

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

05/09/2020

Date of study closure: Type

Anticipated

Date of study closure: Date

25/12/2025

Recruitment status

Pending

Recruitment status: Specify

Date of completion

IPD sharing statement plan

No

IPD sharing statement description

N/A

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Clinicaltrials.gov	NCT03950232
European Clinical Trials Database	EudraCT Number 2018-003987-29

Sources of Monetary or Material Support

Name
Arena Pharmaceuticals Inc. USA

Secondary Sponsors

Name
N/A

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Hasan Dakkak	Wahat Al Arab Building 3rd floor - Al Arab Street – Barbir – Beirut	Lebanon	0096170027779	hasan.dakkak@iqvia.com	IQVIA
Scientific	Chris Cabell	6154 Nancy Ridge Dr. ▪ San Diego, CA 92121	United States of America	+18584537200	ccabell@arenapharm.com	Arena Pharmaceuticals

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
American University of Beirut Medical Center	Dr. Alaa Sharara	Gastroenterology	Approved
Hotel Dieu de France Hospital	Dr. Cesar Yaghi	Gastroenterology	Approved
Saint George University Medical Center	Dr. Said Farhat	Gastroenterology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
American University of Beirut Medical Center	03/09/2020	Dr. Deborah Mukherji	N/A	009611350000
Saint George Hospital University Medical Center	09/07/2020	Dr. Michel Daher	NA	009611441000
Hotel Dieu de France	03/06/2020	Pr. Sami Richa	cue@usj.edu.lb	009611421229

Countries of Recruitment

Name
Australia
Austria
Belgium
Brazil
Bulgaria
Canada
Chile
China
Croatia
Czech Republic
Denmark
Estonia
France
Germany
Hungary
India
Italy
Republic of Korea

Republic of Moldova
Netherlands
Poland
Portugal
Russian Federation
Republic of Serbia
Slovakia
South Africa
Spain
Taiwan
Thailand
Turkey
Ukraine
United Kingdom
United States of America
Belarus
Latvia
Lithuania
Georgia
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
Ulcerative Colitis	Ulcerative colitis (K51)	Colitis Colitis, Ulcerative Ulcer Gastroenteritis Gastrointestinal Diseases Digestive System Diseases Colonic Diseases Intestinal Diseases Pathologic Processes Inflammatory Bowel Diseases

Interventions

Intervention	Description	Keyword
Drug	APD334 (Etrasimod) 2mg tablet	Etrasimod

Primary Outcomes

Name	Time Points	Measure
Number and Severity of Safety Measures	Up to approximately 5 years	Evaluation of adverse events
Incidence of treatment-emergent adverse events and serious adverse events	Up to approximately 5 years	Evaluation of adverse events
Incidence and severity of laboratory abnormalities, and change from baseline in laboratory values (hematology, serum chemistry, coagulation, and urinalysis)	Up to approximately 5 years	Laboratory tests (hematology, serum chemistry, coagulation, and urinalysis)
Incidence of vital sign abnormalities and changes from baseline	Up to approximately 5 years	Evaluation of vital signs (resting heart rate and systolic and diastolic BP, body temperature, and respiratory rate)

Key Secondary Outcomes

Name	Time Points	Measure
Proportion of Participants Achieving Clinical Remission	Week 52, Week 104, Week 156, Week 208, and Week 260	Mayo Component Sub-scores
Proportion of Participants Achieving Clinical Response	Week 52, Week 104, Week 156, Week 208, and Week 260	Mayo Component Sub-scores
Proportion of Participants Achieving Symptomatic Remission	Week 52, Week 104, Week 156, Week 208, and Week 260	Mayo Component Sub-scores
Proportion of Participants Achieving Non-invasive Response	Week 12, Week 24, Week 36, Week 52, Week 104, Week 156, Week 208, and Week 260	Mayo Component Sub-scores
Proportion of Participants Remaining in Clinical Remission	Week 12, Week 52, Week 104, Week 156, Week 208, and Week 260	Mayo Component Sub-scores
Proportion of Participants Achieving Symptomatic Response	Week 12, Week 24, Week 36, Week 52, Week 104, Week 156, Week 208, and Week 260	Mayo Component Sub-scores
Longitudinal change from both Open-Label Extension and Parent Study	Week 12, Week 24, Week 36, Week 52, Week 104, Week 156, Week 208, and Week 260	Mayo Component Sub-scores
Proportion of Participants With Remission and Response	Week 12, Week 52, up to Week 260	Total Mayo Clinic Score
Percentage of Participants With Histologic Improvement at Each Visit With Endoscopy	Up to approximately Week 260	Geboes, Robarts, and Nancy Histopathology Scores
Percentage of Participants With Histologic Remission at Each Visit With Endoscopy	Up to Week 260	Geboes, Robarts, and Nancy Histopathology Scores
Time to Loss of Response	Up to Week 260	Mayo Component Sub-scores
Proportion of Participants With Improvement in Extraintestinal Manifestations (EIMs) in Participants With EIMs at Baseline	Baseline, Week 12, Week 52, Week 104, Week 156, Week 208, and Week 260	N/A

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files