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

**03/04/2025 10:47:07**

## 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 |

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|---|
| 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**