A Long-term Safety Extension Study of SHP647 in Subjects with Moderate to Severe Ulcerative Colitis or Crohn's Disease

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Main Information

Primary registry identifying number
LBCTR2019090245

Protocol number
SHP647-304

MOH registration number
41110/2019

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

Primary sponsor
Shire Human Genetic Therapies, Inc. ("Shire")

Primary sponsor: Country of origin
USA

Date of registration in primary registry
07/01/2020

Date of registration in national regulatory agency

Public title
A Long-term Safety Extension Study of SHP647 in Subjects with Moderate to Severe Ulcerative Colitis or Crohn's Disease

Acronym
AIDA

Scientific title
A Phase 3 Long-term Safety Extension Study of SHP647 in Subjects with Moderate to Severe Ulcerative Colitis or Crohn's Disease (AIDA)

Acronym
AIDA

Brief summary of the study: English

The rationale for this study, SHP647-304, is to offer access to active treatment to subjects who may have benefited from the treatment at the end of the maintenance study (SHP647-303 or SHP647-307) or to subjects who had received placebo or an insufficient duration of active treatment in an induction study (SHP647-302, or SHP647-306) or have met treatment failure criteria in a maintenance study (SHP647-303 or SHP647-307), while evaluating safety and efficacy of long-term treatment with SHP647 in subjects with moderate to severe UC or CD.

Brief summary of the study: Arabic

هو توفير الوصول إلى العلاج النشط للمواضيع الذين قد استفادوا من العلاج في نهاية ، SHP647-304 ، لأساس المنطقي لهذه الدراسة أو إلى الأشخاص الذين تلقوا الغفل أو مده غير كافيه من العلاج النشط في الدراسة التعريفية (SHP647-307 أو SHP647 الدراسة الصيانة (SHP647-303 أو SHP647-307) ، أو قد استوفت معايير فشل العلاج في دراسة الصيانة (SHP647-306 أو ، SHP647-302) شديده CD أو UC في المواضيع مع معتدله إلى SHP647 في حين تقييم سلامه وفعالية العلاج علي المدى الطويل مع.

Health conditions/problem studied: Specify

Moderate to Severe Ulcerative Colitis or Crohn Disease

Interventions: Specify

All subjects will receive active drug in this study. Eligible subjects entering study SHP647-304 will be assigned to receive either 25 mg or 75 mg of SHP647 every 4 weeks. Allocation is dependent on how the subject entered into this study:

Subjects who completed maintenance study SHP647-303 or SHP647-307 without treatment failure and received either 25 mg or 75 mg of SHP647 every 4 weeks will continue to receive the same dose of SHP647 in this long-term safety extension study. If results for confirmation of treatment failure are pending at the time of the end of study visit in study SHP647-307, sites will have 1 additional week to confirm final status of the subject (treatment failure or not) before enrolling the subject to study SHP647-304.

All other subjects will be randomized using a 1:1 allocation. Randomization will be stratified by indication (UC or CD) and by the status from the study from which they are entering, as follows: (1) did not meet the response criteria (clinical and/or endoscopic response/remission as appropriate) in an induction study; (2) treatment failure in a maintenance study, or (3) maintenance study completion without treatment failure for subjects receiving placebo, to facilitate balance of treatment assignment within each stratum.

Key inclusion and exclusion criteria: Inclusion criteria

Ulcerative Colitis:
1. Subjects and/or their parent or legally authorized representative must have an understanding, ability, and willingness to fully comply with study procedures and restrictions.
2. Subjects must be able to voluntarily provide written, signed, and dated (personally or via a legally authorized representative) informed consent and/or assent, as applicable, to participate in the study.
3. Subjects must have been previously enrolled in study SHP647-302, or SHP647-303, and reached 1 of the following clinical trial milestones:
- Completed the Week 12 visit in induction study SHP647-302, and did NOT achieve a clinical response. Clinical response is defined as: 1) a decrease from baseline in the composite score of patient-reported symptoms using daily e-diary and centrally read endoscopy of at least 2 points and at least 30%, with an accompanying decrease in the subscore for rectal bleeding ≥1 point or a subscore for rectal bleeding ≤1, OR 2) a decrease from the induction study (SHP647-302) baseline total Mayo score of at least 3 points and at least 30%, with an accompanying decrease in the rectal bleeding subscore of at least 1 point or an absolute rectal bleeding subscore of 0 or 1.
- Completed the Week 52 visit in maintenance study SHP647-303.
- Withdrew early from maintenance study SHP647-303 due to treatment failure, defined by an endoscopic subscore that has increased by at least 1 point over baseline in the maintenance study or a value ≥2 plus an increase in clinical subscore (stool frequency + rectal bleeding score) of at least 2 points. Centrally read endoscopic subscores will be used to determine treatment failure.
4. Subjects receiving any treatment(s) for UC described in Section 5.2.1 are eligible provided they have been, and are anticipated to be, on a stable dose for the designated period of time.
Crohn's Disease:
1. Subjects and/or their parent or legally authorized representative must have an understanding, ability, and willingness to fully comply with study procedures and restrictions.
2. Subjects must be able to voluntarily provide written, signed, and dated (personally or via a legally authorized representative) informed consent and/or assent, as applicable, to participate in the study.
3. Subjects must have been previously enrolled in study SHP647-306, or SHP647-307, and reached 1 of the following clinical trial milestones:
•Completed the Week 16 visit in induction study SHP647-306, and did NOT meet the efficacy criteria (clinical and/or endoscopic response/remission as appropriate) for entry into maintenance study SHP647-307.
•Completed the Week 52 visit in maintenance study SHP647-307.
•Withdrew early from maintenance study SHP647-307 due to treatment failure (or were considered to have failed treatment, at the time of the last visit in study SHP647-307), as defined in the SHP647-307 protocol.
4. Subjects receiving any treatment(s) for CD described in Section 5.3.1 are eligible provided they have been, and are anticipated to be, on a stable dose for the designated period of time.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

80

Key inclusion and exclusion criteria: Exclusion criteria

Ulcerative Colitis:
1. Subjects who had major protocol deviation(s) (as determined by the sponsor) in study SHP647-302, or SHP647-303.
2. Subjects who permanently discontinued investigational product because of an AE, regardless of relatedness to investigational product, in study SHP647-302, or SHP647-303.
3. Subjects who are likely to require major surgery for UC.
4. Subjects are females who became pregnant during study SHP647-302, or SHP647-303, females who are planning to become pregnant during the study period, or males or females of childbearing potential not agreeing to continue using appropriate contraception methods through the conclusion of study participation (see Section 4.3).
5. Subjects who do not agree to postpone donation of any organ or tissue, including male subjects who are planning to bank or donate sperm and female subjects who are planning to harvest or donate eggs, for the duration of the study and through 16 weeks after last dose of investigational product.
6. Subjects who, in the opinion of the investigator or the sponsor, will be uncooperative or unable to comply with study procedures.
7. Subjects who have a newly-diagnosed malignancy or recurrence of malignancy (other than resected cutaneous basal cell carcinoma, squamous cell carcinoma, or carcinoma in situ of the uterine cervix that has been treated with no evidence of recurrence).
8. Subjects who have developed any major illness/condition or evidence of an unstable clinical condition (eg, renal, hepatic, hematologic, gastrointestinal [except disease under study], endocrine, cardiovascular, pulmonary, immunologic [eg, Felty's syndrome], or local active infection/infectious illness) that, in the investigator's judgment, will substantially increase the risk to the subject if he or she participates in the study.
9. Subjects with any other severe acute or chronic medical or psychiatric condition or laboratory or electrocardiogram (ECG) abnormality that may increase the risk associated with study participation or investigational product administration or may interfere with the interpretation of study results and, in the judgment of the investigator, would make the subject inappropriate for entry into this study.

10. Subjects with known exposure to Mycobacterium tuberculosis (TB) since testing at screening in study SHP647-302 and who have been advised to require treatment for latent or active disease, but who are without a generally accepted course of treatment.
11. Subjects who are investigational site staff members or relatives of those site staff members or subjects who are sponsor employees directly involved in the conduct of the study.
12. Subjects who are participating in other investigational studies (other than SHP647-302, or SHP647-303) or plan to participate in other investigational studies during long-term extension study SHP647-304.

Crohn's Disease:
1. Subjects who had major protocol deviation(s) (as determined by the sponsor) in study SHP647-306, or SHP647-307.
2. Subjects who permanently discontinued investigational product because of an AE, regardless of relatedness to investigational product, in study SHP647-306, or SHP647-307.
3. Subjects who are likely to require major surgery for CD, or developed acute severe complications of CD (with or without fulfilling the treatment failure criteria in the maintenance study) that required immediate intervention (eg, need for immediate biologic treatment with proven effect) and/or CDAI score >450.
4. Subjects are females who became pregnant during study SHP647-306, or SHP647-307, /females who are planning to become pregnant during the study period, or males or females of childbearing potential not agreeing to continue appropriate contraception methods through the conclusion of study participation (see Section 4.3).
5. Subjects who do not agree to postpone donation of any organ or tissue, including male subjects who are planning to bank or donate sperm and female subjects who are planning to harvest or donate eggs, for the duration of the study and through 16 weeks after last dose of investigational product.
6. Subjects who, in the opinion of the investigator or the sponsor, will be uncooperative or unable to comply with study procedures.
7. Subjects who have a newly-diagnosed malignancy or recurrence of malignancy (other than resected cutaneous basal cell carcinoma, squamous cell carcinoma, or carcinoma in situ of the uterine cervix that has been treated with no evidence of recurrence).
8. Subjects who have developed any major illness/condition or evidence of an unstable clinical condition (eg, renal, hepatic, hematologic, gastrointestinal [except disease under study], endocrine, cardiovascular, pulmonary, immunologic [eg, Felty's syndrome], or local active infection/infectious illness) that, in the investigator's judgment, will substantially increase the risk to the subject if he or she participates in the study.
9. Subjects with any other severe acute or chronic medical or psychiatric condition or laboratory or electrocardiogram (ECG) abnormality that may increase the risk associated with study participation or investigational product administration or may interfere with the interpretation of study results and, in the judgment of the investigator, would make the subject inappropriate for entry into this study.
10. Subjects with known exposure to Mycobacterium tuberculosis (TB) since testing at screening in study SHP647-306 and who have been advised to require treatment for latent or active disease, but who are without a generally accepted course of treatment.
11. Subjects who are investigational site staff members or relatives of those site staff members or subjects who are sponsor employees directly involved in the conduct of the study.
12. Subjects who are participating in other investigational studies (other than SHP647-306, or SHP647-307) or plan to participate in other investigational studies during long-term extension study SHP647-304.

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

Randomized controlled trial

Study design: Masking

Blinded (masking used)

Study design: Control

Active

Study phase

3

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Parallel

Study design: Specify assignment

N/A

IMP has market authorization

No

IMP has market authorization: Specify

Name of IMP

Ontamalimab

Year of authorization

Month of authorization

Type of IMP

Immunological

Pharmaceutical class

IgG2 monoclonal antibody

Therapeutic indication

Ulcerative Colitis and Crohn's Disease

Therapeutic benefit

Efficacy will be assessed regularly for all subjects to allow monitoring of clinical benefit derived and evaluation of potential treatment failure throughout the study. To ensure that placebo-treated subjects from a feeder study (SHP647-302, SHP647-303, SHP647-306, or SHP647-307) have sufficient exposure to active drug to permit assessment of response, assessment of treatment failure should not begin prior to Week 12 (for UC) or Week 16 (for CD). Treatment failure should be assessed if there is an unexplained clinical exacerbation or unacceptably low level of clinical response.

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

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

Samples without DNA

Biospecimen description

N/A

Target sample size

8

Actual enrollment target size

Date of first enrollment: Type

Actual

Date of first enrollment: Date

15/03/2020

Date of study closure: Type

Actual

Date of study closure: Date

Recruitment status

Other

Recruitment status: Specify

Study in not initiated yet

Date of completion

09/06/2022

IPD sharing statement plan

No

IPD sharing statement description

Not decided yet

Additional data URL

NA

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
No Numbers	No numbers

Sources of Monetary or Material Support

Name
Shire Human Genetic Therapies, Inc. ("Shire")

Secondary Sponsors

Name
None

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Aziz Zoghbi	MCT Lebanon s.a.r.l.	Lebanon	01--612500 ext2040	Zog_Az@Mctcro.com	CRO
Scientific	Shire Human Genetic Therapies, Inc. US US	300 Shire Way Lexington Post code MA 02421	United States of America	+1 781 482 0852	chantal.letourneau@shire.com	sponsor "Clinical Trial Information Desk"

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Rafik Hariri University Hospital	Dr. Iyad Issa	Gastroenterologist	Approved
Hotel Dieu de France	Dr. Cesar Yaghi	Gastroenterologist	Approved
Hammoud Hospital University Medical Center	Dr. Hassan Atwi	Gastroenterologist	Approved
Al Zahraa University Hospital	Dr. Mahmoud Hallal	Gastroenterologist	Approved
Hammoud Hospital University Medical Center	Dr. Majed Bahlawan	Gastroenterologist	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Rafic Hariri University Hospital	17/05/2019	Abir Sinno	abir.sinno@crurhuh.com	+961 1 830000 ext 2037
Hotel Dieu de France	06/06/2019	Virginia El khoury	Virginia.elkhoury@usj.edu.lb	+961 1 421229
Al Zahraa University Hospital	05/12/2019	Dr. Bassam Mansour	dr.bassammansour@gmail.com	+961 76171272
Hammoud Hospital University Medical Center	15/07/2019	Ghada Aoun	medical@hammoudhospital.org	+961 7 721 021 ext 1956

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
Ulcerative Colitis	Ulcerative colitis (K51)	UC
Crohn's Disease	Crohn s disease, unspecified (K50.9)	CD

Interventions

Intervention	Description	Keyword
SHP647 25mg	SHP647 will be administered subcutaneously in a PFS 1ml	Subjects who completed maintenance study SHP647-303 or SHP647-307 without treatment failure (as defined in the maintenance protocols) and received 25 mg of SHP647 every 4 weeks will continue to receive the same dose of SHP647 in this extension study. All other subjects will be randomized to either 25 mg or 75 mg SHP647 using a 1:1 allocation in this study.
SHP647 75mg	SHP647 will be administered subcutaneously in a PFS 1ml	Subjects who completed maintenance study SHP647-303 or SHP647-307 without treatment failure (as defined in the maintenance protocols) and received 75 mg of SHP647 every 4 weeks will continue to receive the same dose of SHP647 in this extension study. All other subjects will be randomized to either 25 mg or 75 mg SHP647 using a 1:1 allocation in this study.

Primary Outcomes

Name	Time Points	Measure
The primary objective of the study is to evaluate the safety and tolerability of long-term treatment with SHP647 in subjects with moderate to severe UC or CD.	weeks 12, 24, 36, 60, 72, 84...	Safety will be measured by: incidence and severity of adverse events (AEs); incidence and nature of serious infections; actual values and change from baseline, as well as the incidence of abnormalities, in laboratory tests, ECGs, and vital signs; and antidrug antibodies.

Key Secondary Outcomes

Name	Time Points	Measure
Remission based on composite score. Remission is defined as a composite score of patient-reported symptoms using daily diary and locally read endoscopy as follows: stool frequency subscore of 0 or 1 with at least a 1-point change from induction study (SHP647-302) baseline AND rectal bleeding subscore of 0 AND locally-read endoscopic subscore of 0 or 1 (modified, excludes friability).	yearly and at EOS	UC_Remission based on composite score.
Remission, based on total Mayo score. Remission is defined as a total Mayo score ≤ 2 with no individual subscore (stool frequency, rectal bleeding, endoscopy [modified, excludes friability], and physician's global assessment) exceeding 1.	yearly and at EOS	UC_Remission, based on total Mayo score
Clinical remission as defined by stool frequency subscore of 0 or 1 with at least a 1-point change from induction study (SHP647-302) baseline in stool frequency subscore, and rectal bleeding subscore of 0.	yearly and at EOS	UC_Clinical remission
Partial Mayo score of ≤2 with no individual subscore >1 over time. The partial Mayo score does not include the endoscopy subscore.	Over time	UC_Partial Mayo score of ≤2
Endoscopic remission, as defined by locally read endoscopic subscore 0 or 1 (modified, excludes friability).	yearly and at EOS	UC_Endoscopic remission
Clinical remission. it is defined by 2-item PRO CD daily e-diary subscore of average worst daily abdominal pain ≤3 (based on 11-point NRS over the 7 most recent days) and average daily stool frequency ≤2 of type 6/7 (very soft stools/liquid stools) as shown in the BSFS over the 7 most recent days.	Over time	CD_Clinical remission over time.
Enhanced endoscopic response as measured by a decrease in SES-CD of at least 50% from induction study (SHP647-306) baseline	yearly and at EOS	CD_Enhanced endoscopic response.
Clinical remission over time as measured by CDAI <150.	Over time	CD_Clinical remission over time
Clinical remission over time as defined by the following: CD daily e-diary subscores of average worst daily abdominal pain ≤1 (based on the 4-point scale) over the 7 most recent days and average daily stool frequency ≤3 of type 6/7 (very soft stools/liquid stools) as shown in the BSFS over the 7 most recent days.	Over time	CD_Clinical remission over time
Both clinical remission by 2-item PRO and enhanced endoscopic response (composite endpoint).	Over time	CD_Both clinical remission
Complete endoscopic healing defined as SES-CD=0-2.	EOS	CD_Complete endoscopic healing at end of study, defined as SES-CD=0-2.

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