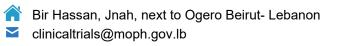
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A study on the Efficacy and Safety of SHP647 as Maintenance Therapy in Subjects With Moderate to Severe Crohn's Disease (CARMEN CD 307)

13/09/2025 19:30:48 Main Information Primary registry identifying number Protocol number LBCTR2019090265 SHP647-307 MOH registration number 3009243/23423 Study registered at the country of origin Study registered at the country of origin: Specify Yes Type of registration Type of registration: Justify Prospective N/A Date of registration in national regulatory agency 12/12/2019 **Primary sponsor** Primary sponsor: Country of origin Shire Human Genetic Therapies, Inc. ("Shire") USA Date of registration in primary registry Date of registration in national regulatory agency 07/01/2020 12/12/2019 Public title Acronym A study on the Efficacy and Safety of SHP647 as Maintenance CARMEN CD 307 Therapy in Subjects With Moderate to Severe Crohn's Disease (CARMEN CD 307) Scientific title Acronym A Phase 3 Randomized, Double-blind, Placebo-controlled, Parallel-CARMEN CD 307 group Efficacy and Safety Study of SHP647 as Maintenance Therapy in Subjects With Moderate to Severe Crohn's Disease (CARMEN CD 307) Brief summary of the study: English This study is designed to evaluate the efficacy of SHP647 as maintenance therapy in subjects with moderate to severe CD who fulfilled the efficacy entry criteria of this study including the clinical and/or endoscopic response criteria defined in induction study SHP647-306. Brief summary of the study: Arabic تم تصميم هذه الدراسة لتقييم فعالية دواء الدراسة كعلاج الصيانة لدى الأشخاص الذين يعانون من مرض كرون المعتدل إلى الشديد والذين استوفوا معايير دخول فعالية هذه الدراسة بما في ذلك معايير الاستجابة السريرية و / أو SHP647-306 . بالمنظار المحددة في الدراسة الحثية Health conditions/problem studied: Specify Moderate to Severe Crohn Disease

Interventions: Specify

This study consists of a 52-week, double-blind treatment period, followed by a 16-week safety follow-up period for subjects who either



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discontinue treatment early or complete the treatment period and do not enter the long-term safety extension (LTS) study (SHP647-304). Eligible subjects who received active treatment in the induction study and fulfilled the efficacy entry criteria of this study, including achieving endoscopic and/or clinical response, will be randomized as follows: subjects who received 25 mg SHP647 in the induction study will be randomized (1:1) to receive either 25 mg SHP647 or placebo, and subjects who received 75 mg SHP647 in the induction study will be randomized (1:1) to receive either 75 mg SHP647 or placebo.

Eligible subjects who received placebo in the induction study and fulfilled the efficacy entry criteria of this study, including achieving endoscopic and/or clinical response, will be randomized in a 2:2:1 ratio to receive 1 of 3 treatments (25 mg SHP647, 75 mg SHP647, or placebo, respectively) during this maintenance study.

Subjects enrolled in this study (SHP647-307) will receive double-blind maintenance treatment in the form of SC injections, using a prefilled syringe (PFS), every 4 weeks for 52 weeks. Subjects will undergo efficacy, biomarker, pharmacokinetic (PK), safety, and health outcome assessments.

Subjects who complete the double-blind treatment period in this maintenance study may be eligible to enter the LTS study (SHP647-304). Subjects who are withdrawn from the study prior to completing the double-blind treatment period due to fulfilling the criteria for treatment failure also may be eligible to enter the LTS study. The intent of providing rescue treatment in the LTS study rather than in this maintenance study following "treatment failure" is to maintain study integrity.

Offering treatment in the LTS study after exiting this maintenance study allows non-responder subjects on placebo, as well as subjects on active study drug, to potentially benefit from a prolonged or different dose of active treatment. Subjects will enter a 16-week safety follow-up period if they withdraw early from the treatment period, are treatment failures and do not choose to enter the LTS study (SHP647-304), or who complete the study and do not wish to enter the LTS study. Treatment failure is defined in Section 4.5.1.

Key inclusion and exclusion criteria: Inclusion criteria

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 completed the 16-week induction treatment period from study SHP647-306 and met the following criteria at baseline in maintenance Study SHP647-307:

a) Meet endoscopic response criteria of a reduction in SES-CD from induction study SHP647-306 baseline by ≥25% at Week 16 of induction study SHP647-306

OR

b) Meet at least 1 of the following 4 criteria at baseline in maintenance study SHP647-307, in addition to no worsening of endoscopic score as measured by SES-CD relative to induction study SHP647-306 baseline:

i. Achieving clinical remission as determined by meeting the criteria for clinical remission using the 2-item PRO, ie, 2-item PRO subscores of average worst daily abdominal pain <3 (based on 11-point numerical rating scale [NRS]) over the 7 most recent days* and average daily stool type frequency ≤2 of type 6/7 (very soft stools/liquid stools) as shown in the BSFS over the 7 most recent days*

ii. A decrease of at least 100 points in CDAI score (CDAI-100) from induction study SHP647-306 baseline.

iii. A decrease of ≥30% and at least 2 points from induction study SHP647-306 baseline in the average daily worst abdominal pain over the 7 most

recent days*, with the average daily stool frequency of type 6/7 (very soft stools/liquid stools) either: (i) not worsening from induction study SHP647-306 baseline and/or (ii) meeting the criteria for clinical remission, ie, 2-item PRO subscore of 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*

iv. A decrease of ≥30% from induction study SHP647-306 baseline in the average daily stool frequency of type 6/7 (very soft stools/liquid stools) as shown in the BSFS over the 7 most recent days*, with the average daily worst abdominal pain either: (i) not worsening from induction study SHP647-306 baseline and/or (ii) meeting the criteria for clinical remission, ie, 2-item PRO subscore of average worst daily abdominal pain ≤3 (based on 11-point NRS) over the 7 most recent days*

*Note: The 7 days may or may not be contiguous during the 10 days of data collection before colonoscopy preparation, depending on days to be excluded because of missing data. If fewer than 7 days are available, the criterion will be calculated on all available most recent 6 or 5 days. If fewer than 5 days are available, the criterion will be treated as missing.

4. Subjects receiving any treatment(s) for CD 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.

Key inclusion and exclusion criteria: Gender	Key inclusion and exclusion criteria: Specify gender
Both	
Key inclusion and exclusion criteria: Age minimum	Key inclusion and exclusion criteria: Age maximum
18	80

Key inclusion and exclusion criteria: Exclusion criteria

1. Subjects who had major protocol deviation(s) (as determined by the sponsor) in induction study SHP647-306.

2. Subjects who permanently discontinued investigational product because of an AE, regardless of relatedness to investigational product, in induction study SHP647-306.

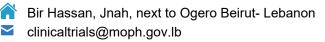
3. Subjects who are likely to require surgery for CD during the study period, except minor interventions (eg, seton placement for anal fistulas).

4. Subjects are females who became pregnant during induction study SHP647-306, 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 (Section 4.4).

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, or 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 developed obstructive colonic stricture, or enterovesical or enterovaginal fistulae during the induction study SHP647-306.



8. Subjects who have a newly diagnosed malignancy or recurrence of malignancy (other than resected cutaneous basal cell carcinoma,

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squamous cell carcinoma, or carcinoma in situ of the uterine cervix that has been treated with no evidence of recurrence).

9. 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.

10. 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.

 Subjects with known exposure to Mycobacterium tuberculosis since testing at screening in induction 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.
 Subjects with any of the following abnormalities in hematology and/or serum chemistry profiles during the evaluation of the last visit in the

12. Subjects with any of the following abnormalities in hematology and/or serum chemistry profiles during the evaluation of the last visit in the SHP647-306 study.

If the results are considered by the investigator to be transient and inconsistent with the subject's clinical condition, may be repeated once prior to enrolment in Study SHP647-307.

□ Alanine aminotransferase and aspartate aminotransferase levels > ou = 3 × the upper limit of

normal (ULN)

□ Total bilirubin level > ou =1.5 × ULN or >2 × ULN if the subject has a known documented history of Gilbert's syndrome

□ Hemoglobin level < ou = 80 g/L (8.0 g/dL)

□ Platelet count < ou = 100 × 109/L (100,000 cells/mm3) or > ou = 1000 × 109/L (1,000,000 cells/mm3)*

 \Box White blood cell count < ou = 3.5 × 109/L (3500 cells/mm3)

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□ Absolute neutrophil count<2 × 109/L (<2000 cells/mm3)

□ Serum creatinine level >1.5 × ULN or estimated glomerular filtration rate <30 mL/min/1.73 m2 based on the abbreviated Modification of Diet in Renal Disease Study Equation.

*Note: If platelet count is <150,000 cells/mm3, a further evaluation should be performed to rule out cirrhosis, unless another etiology has already been identified.

13. 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.

14. Subjects who are participating in other investigational studies (other than induction study SHP647-306 or plan to participate in other investigational studies during Study SHP647-307.

Type of study

Interventional

Type of intervention Pharmaceutical	Type of intervention: Specify type N/A		
Trial scope	Trial scope: Specify scope		
Therapy	N/A		
Study design: Allocation	Study design: Masking		
Randomized controlled trial	Blinded (masking used)		
Study design: Control	Study phase		
Active	3		
Study design: Purpose	Study design: Specify purpose		
Treatment	N/A		
Study design: Assignment	Study design: Specify assignment		
Parallel	N/A		
IMP has market authorization No	IMP has market authorization: Specify		
Name of IMP	Year of authorization Month of authorization		
Ontamalimab			
Type of IMP			
Immunological			

Pharmaceutical class IgG2 Monoclonal antibody



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Therapeutic indication

Crohn Disease

Therapeutic benefit

This study is designed to evaluate the efficacy of SHP647 as maintenance moderate to severe CD who fulfilled the efficacy entry criteria of this study endoscopic response criteria defined in induction study SHP647-306. The design of the maintenance study (SHP647-307) for those who completenduction study SHP647-306 and met entry criteria is one of randomized with subject may be randomized to continue treatment on the same dose of act placebo. This design allows for the assessment of the total and multidimer drug, which encompass efficacy, safety, convenience, and other factors like of the drug. As one of the coprimary objectives of this study is clinical remission, reransubjects from the induction study SHP647-306 who meet entry criteria for (SHP647-307) allows for the greatest number of subjects to potentially be Rerandomizing placebo-treated subjects who qualify for the maintenance sumber of subjects to potentially benefit from treatment with active treatment Additionally, randomized withdrawal of subjects on active treatment and retreated subjects entering the maintenance study allows for a full and separinduction of clinical remission and maintenance of clinical remission effects treatment for CD, such as SHP647. Rerandomizing placebo-treated subjects investigation of long-term safety of SHP647.	including the clinical and/or eted active treatment in the vithdrawal, whereby a tive treatment or switched to nsional benefits of a new ke the durability of the effect domizing placebo-treated the maintenance study in clinical remission. study allows for the greatest ent. erandomization of placebo- rate investigation of the s of any potential new
Study model	Study model: Explain model
N/A	N/A
Study model: Specify model N/A	
Time perspective	Time perspective: Explain time perspective
N/A	N/A
Time perspective: Specify perspective N/A	
Target follow-up duration	Target follow-up duration: Unit
Number of groups/cohorts	
Biospecimen retention	Biospecimen description
Samples without DNA	N/A
Target sample size 4	Actual enrollment target size
Date of first enrollment: Type	Date of first enrollment: Date
Actual	30/03/2020
Date of study closure: Type	Date of study closure: Date

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Actual	31/01/2023
Recruitment status Other	Recruitment status: Specify Study not initiated yet
Date of completion 26/08/2022	
IPD sharing statement plan	IPD sharing statement description
No	Not decided yet
Additional data URL	
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	



Contac	t for Public/Scientific Queries	5				
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.letournea u@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
Al Zahraa University Hospital	Dr. Mahmoud Hallal	Gastroenterologist	NA
Hammoud Hospital University Medical Center	Dr. Majed Bahlawan	Gastroenterologist	Approved

Ethics Review				
Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hammoud Hospital University Medical Center	15/07/2019	ghada aoun	medical@hammoudhospital.org	+9617721021

Countries of Recruitment
Name
Lebanon
Australia
United States of America
Austria
Belgium
Bulgaria
Croatia
Czech Republic
Estonia
Germany

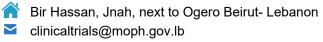




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Colombia
Japan
Mexico
New Zealand
Russian Federation
Republic of Serbia
South Africa
Democratic People Republic of Korea
Ukraine

Health Conditions or Problems Studied				
Condition	Code	Keyword		
Crohn Disease	Crohn s disease, unspecified (K50.9)	CD		





Interventions			
Intervention	Description	Keyword	
SHP647 25 mg	SHP647 will be administered subcutaneously in a PFS 1ml	subjects who received 25 mg SHP647 in one of the induction studies will be randomized (1:1) to receive either 25 mg SHP647 or placebo	
SHP647 75 mg	SHP647 will be administered subcutaneously in a PFS 1ml	subjects who received 75 mg SHP647 in one of the induction studies will be randomized (1:1) to receive either 75 mg SHP647 or placebo.	
Placebo	The placebo solution will contain the same sterile aqueous buffered solution as the test product but will not contain SHP647	Subjects who fulfill all eligibility criteria and who received placebo in the induction study will be randomized in a 2:2:1 ratio to receive 1 of 3 treatments (25 mg SHP647, 75 mg SHP647, or placebo, respectively) during this maintenance study.	

Primary Outcomes				
Name	Time Points	Measure		
Clinical remission	week 52	Clinical remission, as measured by a decrease below prespecified thresholds in the 2-item PRO (abdominal pain severity and very soft stool/liquid stool frequency [as shown in the BSFS]).		
Enhanced endoscopic response	week 52	Enhanced endoscopic response, as measured by a decrease in SES-CD.		

Key Secondary Outcomes

They become any butcomes				
Name	Time Points	Measure		
Clinical Remission defined by CDAI score	week 52	Clinical Remission defined by CDAI score at week 52		
Glucocorticoid-free Clinical Remission Based on Patient- reported Clinical Signs and Symptoms (2-item PRO)	Week 52	Glucocorticoid-free Clinical Remission at week 52		
Clinical Remission Defined by Average Daily Abdominal Pain ≤1 (Based on the 4-point Scale) and Average Daily Stool Frequency ≤3 of Type 6/7	Week 52	Clinical Remission at week 52		
Clinical Remission Among Subjects in Clinical Remission at Baseline of the SHP647-307 Study, Based on Patient- reported Clinical Signs and Symptoms (2-Item PRO)	Week 52	Clinical Remission at week 52		
Enhanced Endoscopic Response Among Subjects with Enhanced Endoscopic Response at Baseline of the SHP647- 307 Study	Week 52	Enhanced Endoscopic Response at week 52		
Clinical Remission as Well as Enhanced Endoscopic Response in the Same Subject	Week 52	Clinical Remission as Well as Enhanced Endoscopic Response at week 52		
Complete Endoscopic Healing	week 52	Complete Endoscopic Healing at week 52		



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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