ClinicalTrials.gov PRS
Protocol Registration and Results System

ID: 341-201-00004 Efficacy and Safety of Oral OPS-2071 in Participants With Crohn's Disease Showing Symptoms of Active Inflammation NCT03850509

Results Preview

Hide All

Participant Flow

Recruitment Details	Participants were enrolled at 2 investigative sites in the United States and Poland from 25 February 2020 to 22 May 2020.
Pre-assignment Details	Participants with Crohn's disease showing symptoms of active inflammation despite ongoing treatment were enrolled and randomized in this study to receive OPS-2071 300 mg BID and OPS-2071 matched placebo. Participants were also to be randomized in OPS-2071 150 mg and 600 mg, however, the study was terminated before the enrollment of participants in the respective arms.

Arm/Group Title	OPS-2071 300 mg BID	Placebo	Total (Not public)
Arm/Group Description	Participants received OPS-2071 300 mg, tablets, orally, twice daily (BID) in the morning and evening (8 to 12 hours apart) with 240 milliliters (mL) of water for up to 6 weeks.	Participants received OPS-2071-matched placebo, tablets, orally, BID in morning and evening (8 to 12 hours apart) with 240 mL of water for up to 4 weeks.	
Period Title: **Overall Study**			
Started	2	1	3
Completed	0	0	0
Not Completed	2	1	3
Reason Not Completed			
Study Terminated by the Sponsor (Due to COVID-19 Situation)	2	1	3
(Not Public)	Not Completed =2 Total from all reasons =2	Not Completed =1 Total from all reasons =1	

Baseline Characteristics

NOTE : A Study Specific Baseline Measure for an Outcome Measure has not been entered.

Arm/Group Title		OPS-2071 300 mg BID		Placebo		Total	
▼ Arm/Group Description		Participants received OPS-2071 300 mg, tablets, orally, twice daily (BID) in the morning and evening (8 to 12 hours apart) with 240 milliliters (mL) of water for up to 6 weeks.		Participants received OPS-2071-matched placebo, tablets, orally, BID in morning and evening (8 to 12 hours apart) with 240 mL of water for up to 4 weeks.			
Overall Number of Baseline Participants		2		1		3	
▼ Baseline Analysis Population Description		The Randomized Set included all participants who were randomized into this trial.					
Age, Categorical Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	2 participants		1 participants		3 participants	
	<=18 years	0	0%	0	0%	0	0%
	Between 18 and 65 years	2	100%	1	100%	3	100%
	>=65 years	0	0%	0	0%	0	0%
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	2 participants		1 participants		3 participants	
	Female	2	100%	1	100%	3	100%
	Male	0	0%	0	0%	0	0%
Ethnicity (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	2 participants		1 participants		3 participants	

	Hispanic or Latino	0	0%	0	0%	0	0%
	Not Hispanic or Latino	2	100%	1	100%	3	100%
	Unknown or Not Reported	0	0%	0	0%	0	0%
Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	2 participants		1 participants		3 participants	
	American Indian or Alaska Native	0	0%	0	0%	0	0%
	Asian	0	0%	0	0%	0	0%
	Native Hawaiian or Other Pacific Islander	0	0%	0	0%	0	0%
	Black or African American	0	0%	0	0%	0	0%
	White	2	100%	1	100%	3	100%
	More than one race	0	0%	0	0%	0	0%
	Unknown or Not Reported	0	0%	0	0%	0	0%

Outcome Measures

1. Primary Outcome

Title:	Percentage of Participants Who Achieved Clinical Remission Based on Crohn's Disease Activity Index (CDAI) Score

▼ Description:	Clinical remission was defined as CDAI score <150 at Week 12. The CDAI evaluated severity of signs and symptoms of Chron's Disease. Some components of the CDAI were reported by the investigator (physical examination for the presence of an abdominal mass and extraintestinal complications, laboratory results for hematocrit levels, and weight) while other components were determined with data collected in a participant diary (number of liquid or soft stools, number of antidiarrheal medications, abdominal pain score, and general well-being). The index values of 150 and below were associated with quiescent disease; values above that indicated active disease, values >=220 indicated moderate to severe disease, and values above 450 were seen with extremely severe disease. If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.
Time Frame:	Week 12

▼ Outcome Measure Data ✓

▼ Analysis Population Description

This outcome measure was not analyzed as no participants reached Week 12 time point due to early termination of the study.

Arm/Group Title	OPS-2071 300 mg BID	Placebo
▼ Arm/Group Description:	Participants received OPS-2071 300 mg, tablets, orally, twice daily (BID) in the morning and evening (8 to 12 hours apart) with 240 milliliters (mL) of water for up to 6 weeks.	Participants received OPS-2071-matched placebo, tablets, orally, BID in morning and evening (8 to 12 hours apart) with 240 mL of water for up to 4 weeks.
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

2. Secondary Outcome

Title:	Percentage of Participants With Endoscopic Response Based on Simple Endoscopic Score for Crohn's Disease (SES-CD)
▼ Description:	Endoscopic response was defined as a reduction of the SES-CD by at least 50%, at Week 12. The SES-CD is a total score that indicates endoscopic disease activity status based on endoscopy results regarding the size of ulcers, surface ulceration, affected surface size, and presence of luminal narrowing. Each item is scored from 0-3, with total score from 0-60 . Higher score indicates more severe endoscopic activity. If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.
Time Frame:	Week 12

▼ Outcome Measure Data ✓

▼ Analysis Population Description

This outcome measure was not analyzed as no participants reached Week 12 time point due to early termination of the study.

Arm/Group Title	OPS-2071 300 mg BID	Placebo
▼ Arm/Group Description:	Participants received OPS-2071 300 mg, tablets, orally, twice daily (BID) in the morning and evening (8 to 12 hours apart) with 240 milliliters (mL) of water for up to 6 weeks.	Participants received OPS-2071-matched placebo, tablets, orally, BID in morning and evening (8 to 12 hours apart) with 240 mL of water for up to 4 weeks.
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

3. Secondary Outcome

Title:	Change From Baseline in the SES-CD Score at Week 12
▼ Description:	The SES-CD is a total score that indicates endoscopic disease activity status based on endoscopy results regarding the size of ulcers, surface ulceration, affected surface size, and presence of luminal narrowing. Each item is scored from 0-3, with a total score from 0-60. A higher score indicates more severe endoscopic activity. A negative change from baseline indicates improvement. If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.
Time Frame:	Baseline (Day 1) and Week 12

▼ Outcome Measure Data ✓

▼ Analysis Population Description

This outcome measure was not analyzed as no participants reached Week 12 time point due to early termination of the study.

Arm/Group Title	OPS-2071 300 mg BID	Placebo
▼ Arm/Group Description:	Participants received OPS-2071 300 mg, tablets, orally, twice daily (BID) in the morning and evening (8 to 12 hours apart) with 240 milliliters (mL) of water for up to 6 weeks.	Participants received OPS-2071-matched placebo, tablets, orally, BID in morning and evening (8 to 12 hours apart) with 240 mL of water for up to 4 weeks.

Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

4. Secondary Outcome

Title:	Percentage of Participants With Two-item Participant Reported Outcome (PRO-2) Remission
▼ Description:	PRO-2 remission was defined as stool frequency =< 3 times per day and abdominal pain =< 1 at Week 12. The PRO-2 is a symptom control measure based on 2 participant-reported components (stool frequency and abdominal pain) of the CDAI (on an 11-point scale where 0=no pain to 10=worst imaginable pain). A weekly score was calculated for the liquid or soft stool frequency and a separate weekly score was calculated for abdominal pain, in each case based on daily symptom reporting. PRO2 is a composite index consisting of weighted scoring of both variables. PRO2 scores ranges from 0 to approximately 45, higher score indicates higher disease activity. If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.
Time Frame:	Week 12

▼ Outcome Measure Data

▼ Analysis Population Description

This outcome measure was not analyzed as no participants reached Week 12 time point due to early termination of the study.

Arm/Group Title	OPS-2071 300 mg BID	Placebo
▼ Arm/Group Description:	Participants received OPS-2071 300 mg, tablets, orally, twice daily (BID) in the morning and evening (8 to 12 hours apart) with 240 milliliters (mL) of water for up to 6 weeks.	Participants received OPS-2071-matched placebo, tablets, orally, BID in morning and evening (8 to 12 hours apart) with 240 mL of water for up to 4 weeks.
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

5. Secondary Outcome

Title:	Percentage of Participants With Clinical Response Based on CDAI Score

▼ Description:	Clinical response was defined as at least a 25% decrease in the CDAI score at Week 12. The CDAI evaluated the severity of signs and symptoms of Chron's Disease. Some components of the CDAI were reported by the investigator (physical examination for the presence of an abdominal mass and extraintestinal complications, laboratory results for hematocrit levels, and weight) while other components were determined with data collected in a participant diary (number of liquid or soft stools, number of antidiarrheal medications, abdominal pain score, and general well-being). The index values of 150 and below were associated with quiescent disease; values above that indicated active disease, values >=220 indicated moderate to severe disease, and values above 450 were seen with extremely severe disease. If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.
Time Frame:	Week 12

▼ Outcome Measure Data 

▼ Analysis Population Description

This outcome measure was not analyzed as no participants reached Week 12 time point due to early termination of the study.

Arm/Group Title	OPS-2071 300 mg BID	Placebo
▼ Arm/Group Description:	Participants received OPS-2071 300 mg, tablets, orally, twice daily (BID) in the morning and evening (8 to 12 hours apart) with 240 milliliters (mL) of water for up to 6 weeks.	Participants received OPS-2071-matched placebo, tablets, orally, BID in morning and evening (8 to 12 hours apart) with 240 mL of water for up to 4 weeks.
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

6. Secondary Outcome

Title:	Percentage of Participants With Endoscopic Remission Based on SES-CD
▼ Description:	Endoscopic remission was defined as an SES-CD total score of 0 to 2; or a score of 0 to 4, with no individual subscore greater than 1 at Week 12. The SES-CD is a total score that indicates endoscopic disease activity status based on endoscopy results regarding the size of ulcers, surface ulceration, affected surface size, and presence of luminal narrowing. Each item is scored from 0-3, with a total score from 0-60. A higher score indicates more severe endoscopic activity. If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.

Time Frame:	Week 12

▼ Outcome Measure Data ✓

▼ Analysis Population Description

This outcome measure was not analyzed as no participants reached Week 12 time point due to early termination of the study.

Arm/Group Title	OPS-2071 300 mg BID	Placebo
▼ Arm/Group Description:	Participants received OPS-2071 300 mg, tablets, orally, twice daily (BID) in the morning and evening (8 to 12 hours apart) with 240 milliliters (mL) of water for up to 6 weeks.	Participants received OPS-2071-matched placebo, tablets, orally, BID in morning and evening (8 to 12 hours apart) with 240 mL of water for up to 4 weeks.
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

7. Secondary Outcome

Title:	Percentage of Participants With a Decrease in the CDAI Score at Week 12
▼ Description:	Percentage of participants who had a decrease of at least => 100 points in CDAI scores were to be reported. The CDAI evaluated the severity of signs and symptoms of Chron's Disease. Some components of the CDAI were reported by the investigator (physical examination for the presence of an abdominal mass and extraintestinal complications, laboratory results for hematocrit levels, and weight) while other components were determined with data collected in a participant diary (number of liquid or soft stools, number of antidiarrheal medications, abdominal pain score, and general well-being). The index values of 150 and below were associated with quiescent disease; values above that indicated active disease, values >=220 indicated moderate to severe disease, and values above 450 were seen with extremely severe disease. If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.
Time Frame:	Week 12

▼ Outcome Measure Data ✓

▼ Analysis Population Description

This outcome measure was not analyzed as no participants reached Week 12 time point due to early termination of the study.

Arm/Group Title	OPS-2071 300 mg BID	Placebo
▼ Arm/Group Description:	Participants received OPS-2071 300 mg, tablets, orally, twice daily (BID) in the morning and evening (8 to 12 hours apart) with 240 milliliters (mL) of water for up to 6 weeks.	Participants received OPS-2071-matched placebo, tablets, orally, BID in morning and evening (8 to 12 hours apart) with 240 mL of water for up to 4 weeks.
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

8. Secondary Outcome

Title:	Percentage of Participants With at Least One Treatment-Emergent Adverse Event (TEAE) and Serious Adverse Event (SAE)
▼ Description:	An adverse event (AE) is defined as any untoward medical occurrence in a clinical trial participant and that does not necessarily have a causal relationship with the treatment. An SAE is defined as any fatal; life-threatening; persistently or significantly disabling or incapacitating; required in-patient hospitalization or prolonged hospitalization; a congenital anomaly/birth defect; or other medically significant event that, based upon appropriate medical judgment, may have jeopardized the subject and may have required medical or surgical intervention. A TEAE is defined as an AE that occurred after the administration of investigational medicinal product (IMP).
Time Frame:	From the signing of the informed consent form up to early termination (up to approximately 9 weeks)

▼ Outcome Measure Data 

▼ Analysis Population Description

Safety Population included all participants who were administered at least one dose of IMP.

Arm/Group Title	OPS-2071 300 mg BID	Placebo
▼ Arm/Group Description:	Participants received OPS-2071 300 mg, tablets, orally, twice daily (BID) in the morning and evening (8 to 12 hours apart) with 240 milliliters (mL) of water for up to 6 weeks.	Participants received OPS-2071-matched placebo, tablets, orally, BID in morning and evening (8 to 12 hours apart) with 240 mL of water for up to 4 weeks.
Overall Number of Participants Analyzed	2	1
Measure Type: Number Unit of Measure: percentage of participants	50.0	0

Adverse Events

Time Frame	From the signing of the informed consent form up to early termination (up to approximately 9 weeks)
Adverse Event Reporting Description	Safety Analysis Set (SAS) population included all participants who were administered at least one dose of the investigational medicinal product (IMP).
Source Vocabulary Name for Table Default	MedDRA 23.0
Collection Approach for Table Default	Systematic Assessment

Arm/Group Title	OPS-2071 300 mg BID	Placebo
▼ Arm/Group Description	Participants received OPS-2071 300 mg, tablets, orally, twice daily (BID) in the morning and evening (8 to 12 hours apart) with 240 milliliters (mL) of water for up to 6 weeks.	Participants received OPS-2071-matched placebo, tablets, orally, BID in morning and evening (8 to 12 hours apart) with 240 mL of water for up to 4 weeks.

All-Cause Mortality

	OPS-2071 300 mg BID		Placebo	
	Affected / at Risk (%)		Affected / at Risk (%)	
Total	0/2 (0%)		0/1 (0%)	

▼ Serious Adverse Events

	OPS-2071 300 mg BID		Placebo	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	0/2 (0%)		0/1 (0%)	

▼ Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	0%			
	OPS-2071 300 mg BID		**Placebo**	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	1/2 (50%)		0/1 (0%)	
Gastrointestinal disorders				
Flatulence † A	1/2 (50%)	1	0/1 (0%)	0

† Indicates events were collected by systematic assessment.

A Term from vocabulary, Select 0

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Sponsor reserves the right to review results publications prior to public release and can delay such publications for a period greater than 60 days but no more than 120 days from the date that the publication is submitted to the Sponsor for review. Sponsor can require changes to the publication to protect Sponsor's intellectual property rights and/or confidential information and reserves the right to limit publication timing and scope of data published based on the number of study locations.

Results Point of Contact

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