ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
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Efficacy and Safety of SPD476 in Maintaining Remission in Patients With Ulcerative Colitis

This study has been completed.

Sponsor:	Shire
Collaborators:	
Information provided by:	Shire
ClinicalTrials.gov Identifier:	NCT00151892

Purpose

Ulcerative colitis is a disease of the large bowel (colon) and rectum in which the lining of the bowel becomes red and swollen. Over time, patients with this disease may experience acute episodes of diarrhea, rectal bleeding and abdominal pain followed by periods of time without disease symptoms. 5-ASA drugs are a standard treatment for ulcerative colitis. Mesalazine is an experimental drug designed to gradually release 5-ASA into the areas of large bowel associated with ulcerative colitis. This study will test the safety and efficacy of mesalazine in keeping ulcerative colitis in remission.

Condition	Intervention	Phase
Colitis, Ulcerative	Drug: SPD476 Drug: Asacol	Phase 3

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Randomized, Safety/Efficacy Study
Official Title: A Phase III, Randomized Multi-centre, Double-blind, Parallel Group, Active Comparator Study to Compare the Efficacy and Safety of SPD476 (Mesalazine)2.4g/Day Once Daily With Asacol 1.6g/Day Twice Daily in the Maintenance of Remission in Patients With Ulcerative Colitis

Further study details as provided by Shire:

Primary Outcome Measure:

- Endoscopic Remission of Ulcerative Colitis (UC) at 6 Months [Time Frame: 6 Months] [Designated as safety issue: No]

Endoscopic remission is defined as an endoscopy score of less than or equal to 1. Endoscopy score (mucosal appearance) ranges from 0-3 (0 = normal [intact vascular pattern; no friability or granulation], 1 = mild [erythema; decreased vascular pattern; minimal granularity], 2 = moderate [marked erythema; granularity; friability; absent vascular pattern; bleeding with minimal trauma; no ulcerations], 3 = severe [ulceration; spontaneous bleeding].

Secondary Outcome Measures:

- Withdrawal Due to Relapse of UC [Time Frame: Over 6 Months] [Designated as safety issue: No]
  Relapse is defined as withdrawal from the study due to lack of efficacy.
- Endoscopic Remission of UC With No or Mild Symptoms at 6 Months [Time Frame: 6 Months] [Designated as safety issue: No]
  Endoscopic remission with no or mild symptoms is defined as an endoscopy score of less than or equal to 1 and a combined symptom score (stool frequency plus rectal bleeding) of less than or equal to 1. Endoscopy score (mucosal appearance) ranges from 0-3 (0 = normal, 1 = mild , 2 = moderate, 3 = severe). Rectal bleeding is assessed on a scale from 0-3 (0 = no rectal bleeding, 1 = streaks of blood, 2 = obvious blood, 3 = mostly blood). Stool frequency is assessed on a scale of 0-2 (0 = 0-1 more than normal per day, 1 = 2-3 more than normal per day, 2 = 4 or more than normal per day).
- Change From Baseline in Modified Ulcerative Colitis Disease Activity Index (UCDAI) Score at 6 Months [Time Frame: Baseline and 6 months] [Designated as safety issue: No]
  The modified UCDAI score is the sum of the scores of 4 parameters (stool frequency, rectal bleeding, endoscopy score, and physician global assessment), each scoring between 0 and 3, making 12 the worst score.
- Short Inflammatory Bowel Disease Questionnaire (SIBDQ) Total Score [Time Frame: 6 Months] [Designated as safety issue: No]
  Quality of life (QoL) was assessed using the SIBDQ. SIBDQ total score is calculated from the sum of 10 questions. Each question is scored on a scale from 1 (poor QoL) to 7 (good QoL) with total scores ranging from 10 to 70. Higher scores indicate better QoL.

Enrollment: 829
Study Start Date: April 2005
Primary Completion Date: September 2009
Study Completion Date: October 2009

Arms	Assigned Interventions
Experimental: SPD476 Mesalazine	Drug: SPD476 2.4 g/day Once Daily (QD) Other Names: Lialda, mesalazine, mesalamine, MMX mesalamine
Active Comparator: Asacol	Drug: Asacol 1.6g/day administered 800 mg Twice Daily (BID) Other Names: mesalamine

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- previous diagnosis of ulcerative colitis confirmed by histology that has been considered to be in remission for => 30 days
- female subjects must be post-menopausal, surgically or biologically sterile, or with a negative urine pregnancy test at screening and on adequate contraception

Exclusion Criteria:

- proctitis
- previous resective colonic surgery
- Crohn's disease
- hypersensitivity to salicylates
- moderate/severe renal impairment

Contacts and Locations

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Investigators

Principal Investigator:	William J Sandborn, MD	Mayo Clinic
Principal Investigator:	Professor Geert D'Haens	Imelda General Hospital

More Information

FDA recall information
http://www.fda.gov/opacom/7alerts.html

FDA Medical Product Safety Alerts

http://www.fda.gov/Medwatch/SAFETY/2007/safety07.htm

FDA-approved label
http://www.lialda.com/Professional/pdf/pi.pdf

Responsible Party: Shire Pharmaceutical (Timothy Whitaker, M.D.)
Study ID Numbers: SPD476-304
2004-004184-29 [EudraCT Number]
Health Authority: United States: Food and Drug Administration

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Study Results

Participant Flow

Reporting Groups

	Description
SPD476	2.4 g/day once daily (QD)
Asacol	1.6g/day administered 800 mg twice daily (BID)

Overall Study

	SPD476	Asacol
Started	416	413
Completed	340	330
Not Completed	76	83
Lack of Efficacy	50	57
Patient request	10	7
Lost to Follow-up	5	10
Adverse Event	6	3
Protocol Violation	3	3
Non-compliance	0	1
Pregnancy	0	1
Did not return for a visit	1	0
Used prohibited corticosteroids	1	0

	SPD476	Asacol
Lack of study medication at center	0	1

Baseline Characteristics

Reporting Groups

	Description
SPD476	2.4 g/day QD
Asacol	1.6g/day administered 800 mg BID

Baseline Measures

	SPD476	Asacol	Total
Number of Participants	415	411	826
Age, Customized [1] [units: participants]			
<18 years	0	0	0
18 to 64 years	380	377	757
>=65 years	35	34	69
Age, Continuous [1] [units: years] Mean (Standard Deviation)	45.0 (14.05)	45.2 (13.44)	45.1 (13.74)
Gender, Male/Female [1] [units: participants]			
Female	203	197	400
Male	212	214	426
Region of Enrollment [1] [units: participants]			
United States	24	22	46
Taiwan	1	0	1
Spain	3	4	7
Chile	4	4	8
Russian Federation	51	49	100

	SPD476	Asacol	Total
India	81	83	164
France	2	3	5
Denmark	6	5	11
Australia	4	3	7
Peru	7	7	14
South Africa	18	17	35
Netherlands	1	0	1
Korea, Republic of	17	14	31
United Kingdom	7	7	14
Hungary	25	25	50
Czech Republic	50	54	104
Mexico	7	10	17
Canada	15	14	29
Argentina	4	2	6
Brazil	25	28	53
Belgium	11	11	22
Poland	29	31	60
Singapore	3	4	7
Romania	11	10	21
Germany	2	1	3
New Zealand	4	2	6
Sweden	3	1	4

[1] Baseline characteristics were calculated from the Safety Population (n = 826) defined as all randomized subjects who received at least 1 dose of investigational product.

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Endoscopic Remission of Ulcerative Colitis (UC) at 6 Months

Measure Description	Endoscopic remission is defined as an endoscopy score of less than or equal to 1. Endoscopy score (mucosal appearance) ranges from 0-3 (0 = normal [intact vascular pattern; no friability or granulation], 1 = mild [erythema; decreased vascular pattern; minimal granularity], 2 = moderate [marked erythema; granularity; friability; absent vascular pattern; bleeding with minimal trauma; no ulcerations], 3 = severe [ulceration; spontaneous bleeding].
Time Frame	6 Months
Safety Issue?	No

Analysis Population Description

Per Protocol Population (PP) defined as all subjects who either completed the study or withdrew for reasons related to efficacy or AEs and who were deemed to be protocol-compliant.

Reporting Groups

	Description
SPD476	2.4 g/day QD
Asacol	1.6g/day administered 800 mg BID

Measured Values

	SPD476	Asacol
Number of Participants Analyzed	343	336
Endoscopic Remission of Ulcerative Colitis (UC) at 6 Months [units: percent of participants]	83.7	81.5

Statistical Analysis 1 for Endoscopic Remission of Ulcerative Colitis (UC) at 6 Months

Statistical Analysis Overview	Comparison Groups	SPD476, Asacol
	Comments	The null hypothesis to be tested is that the true difference in proportions is less than or equal to -10%.
	Non-Inferiority or Equivalence Analysis?	Yes
	Comments	A 2-sided 95% confidence interval (CI) for the difference in the percentages of subjects in remission at 6 months of the two treatment groups will be computed. Non-inferiority of SPD476 to Asacol will be concluded if the lower limit of the 95% CI lies above the non-inferiority margin of -10%.

Method of Estimation	Estimation Parameter	Other [Difference in proportions]
	Estimated Value	0.02
	Confidence Interval	(2-Sided) 95%

		-0.04 to 0.08
	Estimation Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Withdrawal Due to Relapse of UC
Measure Description	Relapse is defined as withdrawal from the study due to lack of efficacy.
Time Frame	Over 6 Months
Safety Issue?	No

Analysis Population Description
PP

Reporting Groups

	Description
SPD476	2.4 g/day QD
Asacol	1.6g/day administered 800 mg BID

Measured Values

	SPD476	Asacol
Number of Participants Analyzed	343	336
Withdrawal Due to Relapse of UC [units: percent of participants]	12.8	14.6

3. Secondary Outcome Measure:

Measure Title	Endoscopic Remission of UC With No or Mild Symptoms at 6 Months
Measure Description	Endoscopic remission with no or mild symptoms is defined as an endoscopy score of less than or equal to 1 and a combined symptom score (stool frequency plus rectal bleeding) of less than or equal to 1. Endoscopy score (mucosal appearance) ranges from 0-3 (0 = normal, 1 = mild , 2 = moderate, 3 = severe). Rectal bleeding is assessed on a scale from 0-3 (0 = no rectal bleeding, 1 = streaks of blood, 2 = obvious blood, 3 = mostly blood). Stool frequency is assessed on a scale of 0-2 (0 = 0-1 more than normal per day, 1 = 2-3 more than normal per day, 2 = 4 or more than normal per day).
Time Frame	6 Months
Safety Issue?	No

Analysis Population Description
PP

Reporting Groups

	Description
SPD476	2.4 g/day QD
Asacol	1.6g/day administered 800 mg BID

Measured Values

	SPD476	Asacol
Number of Participants Analyzed	343	336
Endoscopic Remission of UC With No or Mild Symptoms at 6 Months [units: percent of participants]	79.0	75.6

4. Secondary Outcome Measure:

Measure Title	Change From Baseline in Modified Ulcerative Colitis Disease Activity Index (UCDAI) Score at 6 Months
Measure Description	The modified UCDAI score is the sum of the scores of 4 parameters (stool frequency, rectal bleeding, endoscopy score, and physician global assessment), each scoring between 0 and 3, making 12 the worst score.
Time Frame	Baseline and 6 months
Safety Issue?	No

Analysis Population Description
PP

Reporting Groups

	Description
SPD476	2.4 g/day QD
Asacol	1.6g/day administered 800 mg BID

Measured Values

	SPD476	Asacol
Number of Participants Analyzed	290	281
Change From Baseline in Modified Ulcerative Colitis Disease Activity Index (UCDAI) Score at 6 Months [units: Units on a scale]	0.061 (1.1516)	0.059 (1.2394)

	SPD476	Asacol
Mean (Standard Deviation)		

5. Secondary Outcome Measure:

Measure Title	Short Inflammatory Bowel Disease Questionnaire (SIBDQ) Total Score
Measure Description	Quality of life (QoL) was assessed using the SIBDQ. SIBDQ total score is calculated from the sum of 10 questions. Each question is scored on a scale from 1 (poor QoL) to 7 (good QoL) with total scores ranging from 10 to 70. Higher scores indicate better QoL.
Time Frame	6 Months
Safety Issue?	No

Analysis Population Description

Intent to treat (ITT) population defined as all randomized subjects who received at least 1 dose of investigational product. Analysis includes patients who completed an SIBDQ questionnaire at 6 months.

Reporting Groups

	Description
SPD476	2.4 g/day QD
Asacol	1.6g/day administered 800 mg BID

Measured Values

	SPD476	Asacol
Number of Participants Analyzed	155	155
Short Inflammatory Bowel Disease Questionnaire (SIBDQ) Total Score [units: Units on a scale] Mean (Standard Deviation)	59.523 (8.7582)	59.664 (7.7440)

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	Safety population defined as all randomized subjects who received at least 1 dose of investigational medication.

Reporting Groups

	Description
SPD476	2.4 g/day QD
Asacol	1.6g/day administered 800 mg BID

Serious Adverse Events

	SPD476	Asacol
	Affected/At Risk (%)	Affected/At Risk (%)
Total	6/415 (1.45%)	3/411 (0.73%)
Gastrointestinal disorders		
Colitis	1/415 (0.24%)	0/411 (0%)
Colitis ulcerative	1/415 (0.24%)	1/411 (0.24%)
Infections and infestations		
Appendicitis	1/415 (0.24%)	0/411 (0%)
Bronchitis	1/415 (0.24%)	0/411 (0%)
Injury, poisoning and procedural complications		
Fallopian tube perforation	0/415 (0%)	1/411 (0.24%)
Post procedural hemorrhage	1/415 (0.24%)	0/411 (0%)
Musculoskeletal and connective tissue disorders		
Intervertebral disc protrusion	0/415 (0%)	1/411 (0.24%)
Nervous system disorders		
Radiculitis brachial	1/415 (0.24%)	0/411 (0%)
Pregnancy, puerperium and perinatal conditions		
Ectopic pregnancy	0/415 (0%)	1/411 (0.24%)
Respiratory, thoracic and mediastinal disorders		
Asthma	1/415 (0.24%)	0/411 (0%)

Other Adverse Events
Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	SPD476	Asacol
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/415 (0%)	0/411 (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.

If a multicenter publication is not submitted within twelve (12) months after conclusion, abandonment or termination of the Study at all sites, or after Sponsor confirms there shall be no multicenter Study publication, the Institution and/or such Principal Investigator may publish the results from the Institution site individually.

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