ID: T-EE05-135 Efficacy and Safety of Dexlansoprazole MR Compared to Placebo on Maintaining Healing in Subjects With Healed Erosive Esophagitis NCT00321737

Results Preview

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Participant Flow

Recruitment Details: Subjects were enrolled at a total of 94 sites: 75 sites in the United States and 19 sites in Australia, Canada, the Czech Republic, Estonia, India, Latvia, Lithuania, Poland, and the Slovak Republic (date of first dose: 19 May 2006; date of last procedure: 21 May 2007).

Pre-Assignment Details: Subjects had to have endoscopically proven healed erosive esophagitis (EE) after 4 to 8 weeks of treatment with lansoprazole 30 mg once-daily (QD), dexlansoprazole modified release (MR) 60 mg QD, or dexlansoprazole MR 90 mg QD in the EE healing studies, T-EE04-084 (NCT00251693) and T-EE04-085 (NCT00251719).

Arm/Group Title	**Placebo QD**	**Dexlansoprazole MR 30 mg QD**	**Dexlansoprazole MR 60 mg QD**	Total (Not public)
Arm/Group Description	Placebo capsules, orally, once daily for up to 6 months.	Dexlansoprazole MR 30 mg, capsules, orally, once daily for up to 6 months.	Dexlansoprazole MR 60 mg, capsules, orally, once daily for up to 6 months.	
Period Title: Overall Study				
Started	147	140	158	445
Completed	25	92	104	221
Not Completed	122	48	54	224
Reason Not Completed				
Relapse of Erosive Esophagitis	76	25	19	120
Adverse Event	11	3	6	20
Lost to Follow-up	5	5	6	16
Withdrawal by Subject	19	12	17	48
Protocol Violation	0	0	1	1
Unmet Inclusion/Exclusion Criteria	1	0	0	1
Possible Barrett's Esophagus	2	1	1	4
Therapeutic Failure	6	0	2	8
Pregnancy	0	2	0	2
Noncompliance	2	0	0	2
Subject Request/ Subject Unavailable	0	0	2	2
(Not Public)	Not Completed = 122 Total from all reasons = 122	Not Completed = 48 Total from all reasons = 48	Not Completed = 54 Total from all reasons = 54	

Baseline Characteristics

Arm/Group Title	**Placebo QD**	**Dexlansoprazole MR 30 mg QD**	**Dexlansoprazole MR 60 mg QD**	**Total**
Arm/Group Description	Placebo capsules, orally, once daily for up to 6 months.	Dexlansoprazole MR 30 mg, capsules, orally, once daily for up to 6 months.	Dexlansoprazole MR 60 mg, capsules, orally, once daily for up to 6 months.	
Overall Number of Baseline Participants	147	140	158	**445**
Baseline Analysis Population Description	[Not specified]			
Age, Continuous **Mean (Standard Deviation)** **Units: years**	49.5 (12.94)	47.1 (13.15)	47.9 (11.72)	48.2 (12.60)
Age, Customized **Measure Type: Number** **Units: participants**				
<45 years	50	54	58	162
45 - <65 years	83	75	89	247
≥65 years	14	11	11	36
Gender, Male/Female **Measure Type: Number**				

Units: participants				
Female	75	71	84	230
Male	72	69	74	215
Race (NIH/OMB)				
Measure Type: Number				
Units: participants				
American Indian or Alaska Native	0	0	4	4
Asian	3	3	5	11
Native Hawaiian or Other Pacific Islander	0	0	1	1
Black or African American	4	6	11	21
White	138	127	135	400
More than one race	1	4	2	7
Unknown or Not Reported	1	0	0	1
Ethnicity (NIH/OMB)				
Measure Type: Number				
Units: participants				
Hispanic or Latino	20	21	19	60
Not Hispanic or Latino	127	119	139	385
Unknown or Not Reported	0	0	0	0
Baseline Los Angeles (LA) Classification Grade for Erosive Esophagitis (EE) [1]				
Measure Type: Number				
Units: participants				
A: ≥1 mucosal break <5 mm	51	53	56	160
B: ≥1 mucosal break ≥5 mm	57	46	57	160
C: ≥1 mucosal break <75% of circumference	34	31	39	104
D: ≥1 mucosal break ≥75% of circumference	5	10	6	21

[1] Baseline values from Studies T-EE04-084 (NCT00251693) and T-EE04-085 (NCT00251719), with severity of EE increasing from Grade A to Grade D.

Outcome Measures

1. Primary Outcome

Title: Percentage of Subjects Who Maintained Complete Healing of Erosive Esophagitis as Assessed by Endoscopy - Crude Rate Analysis.

Description: Crude rates analyzed maintenance of healed EE from baseline of this study and considered prematurely discontinued subjects as relapsed.

Time Frame: 6 months

Safety Issue? No

Outcome Measure Data

Analysis Population Description

The crude rate analysis was performed on intent-to-treat (ITT) subjects (subjects from Studies T-EE04-084 or T-EE04-085 with endoscopically proven healed EE who received at least 1 dose of study drug in this study and did not have a gap of >7 days between the EE healing studies and this study) with at least one endoscopy in this maintenance study.

Arm/Group Title	**Placebo QD**	**Dexlansoprazole MR 30 mg QD**	**Dexlansoprazole MR 60 mg QD**
Arm/Group Description:	Placebo capsules, orally, once daily for up to 6 months.	Dexlansoprazole MR 30 mg, capsules, orally, once daily for up to 6 months.	Dexlansoprazole MR 60 mg, capsules, orally, once daily for up to 6 months.
Number of Participants Analyzed	119	125	143
Measure Type: Number			
Units: Percentage of Subjects	14.3	66.4	66.4

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo QD, Dexlansoprazole MR 30 mg QD
	Comments	[Not specified]

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.00001
	Comments	Hochberg's method was used to ensure that the overall 0.0025 level of significance was maintained for the pairwise comparisons between each dexlansoprazole MR dose and placebo.
	Method	Fisher Exact
	Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Placebo QD, Dexlansoprazole MR 60 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.00001
	Comments	Hochberg's method was used to ensure that the overall 0.0025 level of significance was maintained for the pairwise comparisons between each dexlansoprazole MR dose and placebo.
	Method	Fisher Exact
	Comments	[Not specified]

Statistical Analysis 3

Statistical Analysis Overview	**Comparison Groups**	Dexlansoprazole MR 30 mg QD, Dexlansoprazole MR 60 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	>0.99999
	Comments	Statistical significance was determined at the 0.0025 level without adjustment for multiple comparisons.
	Method	Fisher Exact
	Comments	[Not specified]

2. Primary Outcome

Title: Percentage of Subjects Who Maintained Complete Healing of Erosive Esophagitis as Assessed by Endoscopy - Life Table Method

Description: Percentage of subjects who maintained complete healing of erosive esophagitis as assessed by endoscopy. In the life table method, subjects without post-baseline endoscopy were included as censored; subjects who did not have a recurrence of EE and did not complete the study were also considered censored.

Time Frame: 6 months

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Life table method for the maintenance rate of healed EE was performed on ITT subjects and included subjects without post-baseline endoscopy as censored.

Arm/Group Title	**Placebo QD**	**Dexlansoprazole MR 30 mg QD**	**Dexlansoprazole MR 60 mg QD**
Arm/Group Description:	Placebo capsules, orally, once daily for up to 6 months.	Dexlansoprazole MR 30 mg, capsules, orally, once daily for up to 6 months.	Dexlansoprazole MR 60 mg, capsules, orally, once daily for up to 6 months.

Number of Participants Analyzed	145	137	153
Measure Type: Number Units: Percentage of Subjects	27.2	74.9	82.5

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo QD, Dexlansoprazole MR 30 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.00001
	Comments	Hochberg's method was used to ensure that the overall 0.0025 level of significance was maintained for the pairwise comparisons between each dexlansoprazole MR dose and placebo.
	Method	Log Rank
	Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Placebo QD, Dexlansoprazole MR 60 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.00001
	Comments	Hochberg's method was used to ensure that the overall 0.0025 level of significance was maintained for the pairwise comparisons between each dexlansoprazole MR dose and placebo.
	Method	Log Rank
	Comments	[Not specified]

Statistical Analysis 3

Statistical Analysis Overview	**Comparison Groups**	Dexlansoprazole MR 30 mg QD, Dexlansoprazole MR 60 mg QD
	Comments	[Not specified]
	Non-Inferiority	No

	or Equivalence Analysis?	
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.13932
	Comments	Statistical significance was determined at the 0.0025 level without adjustment for multiple comparisons.
	Method	Log Rank
	Comments	[Not specified]

3. Secondary Outcome

Title: Percentage of Days Without Daytime or Nighttime Heartburn as Assessed by Daily Diary-Median.

Description: The percentage was calculated as the days that were heartburn-free out of the total number of days for which either a daytime or nighttime result was reported.

Time Frame: 6 months

Safety Issue? No

Outcome Measure Data

Analysis Population Description

The analysis of 24-hour heartburn-free days was performed on ITT subjects with at least one daytime or nighttime heartburn Yes/No question answered during treatment.

Arm/Group Title	**Placebo QD**	**Dexlansoprazole MR 30 mg QD**	**Dexlansoprazole MR 60 mg QD**
Arm/Group Description:	Placebo capsules, orally, once daily for up to 6 months.	Dexlansoprazole MR 30 mg, capsules, orally, once daily for up to 6 months.	Dexlansoprazole MR 60 mg, capsules, orally, once daily for up to 6 months.
Number of Participants Analyzed	141	132	147
Median (Inter-Quartile Range) Units: Percentage of Days	28.6 (5.9 to 61.8)	96.1 (80.7 to 100.0)	90.9 (66.7 to 99.4)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo QD, Dexlansoprazole MR 30 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.00001
	Comments	The 0.0025 level of significance for this secondary endpoint was controlled using Hochberg's method for comparison of each dexlansoprazole MR dose to placebo.
	Method	Wilcoxon (Mann-Whitney)
	Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Placebo QD, Dexlansoprazole MR 60 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.00001
	Comments	The 0.0025 level of significance for this secondary endpoint was controlled using Hochberg's method for comparison of each

		dexlansoprazole MR dose to placebo.
	Method	Wilcoxon (Mann-Whitney)
	Comments	[Not specified]

Statistical Analysis 3

Statistical Analysis Overview	**Comparison Groups**	Dexlansoprazole MR 30 mg QD, Dexlansoprazole MR 60 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.06730
	Comments	Statistical significance was determined at 0.0025 level without adjustment for multiple comparisons.
	Method	Wilcoxon (Mann-Whitney)
	Comments	[Not specified]

4. Secondary Outcome

Title: Percentage of Days Without Daytime or Nighttime Heartburn as Assessed by Daily Diary-Mean.
Description: The percentage was calculated as the days that were heartburn-free out of the total number of days for which either a daytime or nighttime result was marked.
Time Frame: 6 months
Safety Issue? No

Outcome Measure Data

Analysis Population Description
The analysis of 24-hour heartburn-free days was performed on ITT subjects with at least one daytime or nighttime heartburn Yes/No question answered during treatment.

Arm/Group Title	**Placebo QD**	**Dexlansoprazole MR 30 mg QD**	**Dexlansoprazole MR 60 mg QD**
Arm/Group Description:	Placebo capsules, orally, once daily for up to 6 months.	Dexlansoprazole MR 30 mg, capsules, orally, once daily for up to 6 months.	Dexlansoprazole MR 60 mg, capsules, orally, once daily for up to 6 months.
Number of Participants Analyzed	141	132	147
Mean (Standard Deviation) Units: Percentage of Days	36.0 (32.0)	83.3 (26.5)	78.4 (28.3)

5. Secondary Outcome

Title: Percentage of Days Without Nighttime Heartburn as Assessed by Daily Diary-Median.
Description: The percentage was calculated as the nights that were heartburn-free out of the total number of days for which a nighttime result was marked.
Time Frame: 6 months
Safety Issue? No

Outcome Measure Data

Analysis Population Description
The analysis was performed on ITT subjects with at least one nighttime heartburn Yes/No question answered during treatment.

Arm/Group Title	**Placebo QD**	**Dexlansoprazole MR 30 mg QD**	**Dexlansoprazole MR 60 mg QD**
Arm/Group Description:	Placebo capsules, orally, once daily for up to 6 months.	Dexlansoprazole MR 30 mg, capsules, orally, once daily for up to 6 months.	Dexlansoprazole MR 60 mg, capsules, orally, once daily for up to 6 months.
Number of Participants Analyzed	140	132	147
Median (Inter-Quartile			

Range)			
Units: Percentage of Days	71.7 (19.5 to 92.2)	98.9 (90.9 to 100.0)	96.2 (80.0 to 100.0)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Placebo QD, Dexlansoprazole MR 30 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.00001
	Comments	The 0.0025 level of significance for this secondary endpoint was controlled using Hochberg's method for comparison of each dose to placebo.
	Method	Wilcoxon (Mann-Whitney)
	Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Placebo QD, Dexlansoprazole MR 60 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.00001
	Comments	The 0.0025 level of significance for this secondary endpoint was controlled using Hochberg's method for comparison of each dose to placebo.
	Method	Wilcoxon (Mann-Whitney)
	Comments	[Not specified]

Statistical Analysis 3

Statistical Analysis Overview	**Comparison Groups**	Dexlansoprazole MR 30 mg QD, Dexlansoprazole MR 60 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	**P-Value**	0.11257
	Comments	Statistical significance was determined at the 0.0025 level without adjustment for multiple comparisons.
	Method	Wilcoxon (Mann-Whitney)
	Comments	[Not specified]

6. Secondary Outcome

Title: Percentage of Days Without Nighttime Heartburn as Assessed by Daily Diary-Mean.

Description: The percentage was calculated as the nights that were heartburn-free out of the total number of days for which a nighttime result was marked.

Time Frame: 6 months

Safety Issue? No

Outcome Measure Data

Analysis Population Description

The analysis was performed on ITT subjects with at least one nighttime heartburn Yes/No question answered during treatment.

Arm/Group Title	**Placebo QD**	**Dexlansoprazole MR 30 mg QD**	**Dexlansoprazole MR 60 mg QD**
Arm/Group Description:	Placebo capsules, orally, once daily for up to 6 months.	Dexlansoprazole MR 30 mg, capsules, orally, once daily for up to 6 months.	Dexlansoprazole MR 60 mg, capsules, orally, once daily for up to 6 months.
Number of Participants Analyzed	140	132	147
Mean (Standard Deviation) Units: Percentage of Days	57.7 (36.6)	89.3 (22.3)	86.0 (23.1)

Adverse Events

Time Frame	
Additional Description	
Source Vocabulary Name	[Not specified]
Assessment Type	[Not specified]

Arm/Group Title	Placebo QD	Dexlansoprazole MR 30 mg QD	Dexlansoprazole MR 60 mg QD
Arm/Group Description	Placebo capsules, orally, once daily for up to 6 months.	Dexlansoprazole MR 30 mg, capsules, orally, once daily for up to 6 months.	Dexlansoprazole MR 60 mg, capsules, orally, once daily for up to 6 months.

Serious Adverse Events

	Placebo QD Affected / at Risk (%)	**Dexlansoprazole MR 30 mg QD** Affected / at Risk (%)	**Dexlansoprazole MR 60 mg QD** Affected / at Risk (%)
Total	1/---	2/---	6/---
General disorders			
Implant and Catheter Site Reactions † A	0/147 (0%)	0/140 (0%)	1/158 (0.63%)
Pain and Discomfort Not Elsewhere Classified (NEC) † A	0/147 (0%)	0/140 (0%)	1/158 (0.63%)
Hepatobiliary disorders			
Cholecystitis and Cholelithiasis † A	0/147 (0%)	0/140 (0%)	1/158 (0.63%)
Infections and infestations			
Bacterial Infections NEC † A	0/147 (0%)	0/140 (0%)	1/158 (0.63%)
Viral Infections NEC † A	0/147 (0%)	0/140 (0%)	1/158 (0.63%)
Injury, poisoning and procedural complications			
Limb Injuries NEC (Including [Incl] Traumatic Amputation) † A	0/147 (0%)	0/140 (0%)	1/158 (0.63%)
Non-Site Specific Injuries NEC † A	0/147 (0%)	0/140 (0%)	1/158 (0.63%)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostatic Neoplasms Malignant † A	0/147 (0%)	1/140 (0.71%)	0/158 (0%)
Nervous system disorders			
Cerebrovascular Venous and Sinus Thrombosis † A	0/147 (0%)	0/140 (0%)	1/158 (0.63%)
Migraine Headaches † A	0/147 (0%)	0/140 (0%)	1/158 (0.63%)
Pregnancy, puerperium and perinatal conditions			
Abortions Spontaneous † A	1/147 (0.68%)	1/140 (0.71%)	0/158 (0%)
Reproductive system and breast disorders			
Ovarian And Fallopian Tube Cysts and Neoplasms † A	0/147 (0%)	0/140 (0%)	1/158 (0.63%)
Uterine Disorders NEC † A	0/147 (0%)	0/140 (0%)	1/158 (0.63%)
Respiratory, thoracic and mediastinal disorders			
Bronchospasm and Obstruction † A	0/147 (0%)	0/140 (0%)	1/158 (0.63%)
Vascular disorders			
Peripheral Embolism and Thrombosis † A	0/147 (0%)	0/140 (0%)	1/158 (0.63%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 9.1

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%

	Placebo QD Affected / at Risk (%)	**Dexlansoprazole MR 30 mg QD** Affected / at Risk (%)	**Dexlansoprazole MR 60 mg QD** Affected / at Risk (%)
Total	11/---	26/---	35/---
Gastrointestinal disorders			
Diarrhoea (Excluding [Excl] Infective) † A	1/147 (0.68%)	5/140 (3.57%)	8/158 (5.06%)
Gastritis (Excl Infective) † A	7/147 (4.76%)	2/140 (1.43%)	8/158 (5.06%)
Infections and infestations			
Upper Respiratory Tract Infections † A	1/147 (0.68%)	14/140 (10%)	17/158 (10.76%)
Musculoskeletal and connective tissue disorders			
Joint Related Signs and Symptoms † A	1/147 (0.68%)	7/140 (5%)	0/158 (0%)
Musculoskeletal and Connective Tissue Signs and Symptoms NEC † A	2/147 (1.36%)	3/140 (2.14%)	8/158 (5.06%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 9.1

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.

No publication related to study results will be published prior to publication of a multi-center report submitted for publication within 18 months after conclusion or termination of a study. Results publications will be submitted to sponsor for review 60 days in advance of publication. Sponsor can require removal of confidential information unrelated to study results. Sponsor can embargo a proposed publication for another 60 days to preserve intellectual property.

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