Trial record **1 of 1** for: DUR001-302

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Efficacy and Safety of Dalbavancin for the Treatment of Acute Bacterial Skin and Skin Structure Infections

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT01431339

Recruitment Status : Completed
First Posted : September 9, 2011
Results First Posted : February 12, 2014
Last Update Posted : February 12, 2014

Sponsor:
Durata Therapeutics Inc., an affiliate of Allergan plc

Information provided by (Responsible Party):
Durata Therapeutics Inc., an affiliate of Allergan plc

Study Details | Tabular View | Study Results | Disclaimer

How to Read a Study Record

Study Type:

	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Abscess Wound Infection Surgical Site Infection Cellulitis
Interventions:	Drug: IV Dalbavancin Drug: Vancomycin/Linezolid

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Dalbavancin	IV Dalbavancin: IV Dalbavancin 1000 mg on Day 1 and 500 mg on Day 8
Vancomycin With Possible Switch to Oral Linezolid	Vancomycin/Linezolid: IV Vancomycin (1 gram Q 12 hours or 15mg/Kg Q 12 hours) with optional switch to oral linezolid (600 mg every

	12 hours). Total duration of therapy is 10-14 days

Participant Flow: Overall Study

	Dalbavancin	Vancomycin With Possible Switch to Oral Linezolid
STARTED	**371**	**368**
Safety Population	**368**	**367**
COMPLETED	**332**	**333**
NOT COMPLETED	**39**	**35**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Dalbavancin	IV Dalbavancin: IV Dalbavancin 1000 mg on Day 1 and 500 mg on Day 8
Vancomycin With Possible Switch to Oral Linezolid	Vancomycin/Linezolid: IV Vancomycin (1 gram Q 12 hours or 15mg/Kg Q 12 hours) with optional switch to oral linezolid (600 mg every 12 hours). Total duration of therapy is 10-14 days

Total	Total of all reporting groups

Baseline Measures

	Dalbavancin	Vancomycin With Possible Switch to Oral Linezolid	Total
Overall Participants Analyzed [Units: Participants]	**371**	**368**	**739**
Age [Units: Years] Mean (Standard Deviation)	**49.1 (16.54)**	**51.4 (16.16)**	**50.2 (16.38)**
Gender [Units: Participants]			
Female	**148**	**167**	**315**
Male	**223**	**201**	**424**

Outcome Measures

Hide All Outcome Measures

1. Primary: Early Clinical Efficacy [Time Frame: After 48-72 hours of therapy]

Measure Type	Primary
Measure Title	Early Clinical Efficacy
Measure Description	Clinical response at 48-72 hours post study drug initiation, based on measurements of acute bacterial skin and skin structure infections (ABSSSI) lesion size and temperature
Time Frame	After 48-72 hours of therapy

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The ITT population consisted of all randomly assigned patients regardless of whether or not they received study drug.

Reporting Groups

	Description
Dalbavancin	IV Dalbavancin: IV Dalbavancin 1000 mg on Day 1 and 500 mg on Day 8
Vancomycin With Possible Switch to Oral Linezolid	Vancomycin/Linezolid: IV Vancomycin (1 gram Q 12 hours or 15mg/Kg Q 12 hours) with optional switch to oral linezolid (600 mg every 12 hours). Total duration of therapy is 10-14 days

Measured Values

	Dalbavancin	**Vancomycin With Possible Switch to Oral Linezolid**
Participants Analyzed [Units: Participants]	**371**	**368**
Early Clinical Efficacy [Units: Participants]		
Clinical Responder	**285**	**288**
Clinical Non-Responder	**86**	**80**

Statistical Analysis 1 for Early Clinical Efficacy

Groups [1]	All groups
Statistical Test Type [2]	Non-Inferiority or Equivalence
Difference in Proportions [3]	-1.5
95% Confidence Interval	-7.4 to 4.6

[1] Additional details about the analysis, such as null hypothesis and power calculation:

No text entered.

[2] Details of power calculation, definition of non-inferiority margin, and other key parameters:

The non-inferiority hypothesis test is a one-sided hypothesis test performed at the 2.5% level of significance. If the lower limit of the 95% CI for the difference in response rates in the ITT population is greater than -10% the NI of dalbavancin to vancomycin/linezolid will be concluded.

[3] Other relevant estimation information:

Confidence intervals were adjusted for fever at baseline

2. Secondary: Clinical Status [Time Frame: End of Treatment Visit (Day 14-15)]

Measure Type	Secondary
Measure Title	Clinical Status
Measure Description	Compare the clinical efficacy at end of treatment visit of dalbavancin to the comparator regimen based on lesion size, local signs, temperature and receipt of other therapy
Time Frame	End of Treatment Visit (Day 14-15)

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Clinical Evaluable Population based on certain inclusion/exclusion criteria, length of study therapy, concomitant antibacterials, concomitant surgical procedure and non-missing data.

Reporting Groups

	Description
Dalbavancin	IV Dalbavancin: IV Dalbavancin 1000 mg on Day 1 and 500 mg on Day 8
Vancomycin With Possible Switch to Oral Linezolid	

	Vancomycin/Linezolid: IV Vancomycin (1 gram Q 12 hours or 15mg/Kg Q 12 hours) with optional switch to oral linezolid (600 mg every 12 hours). Total duration of therapy is 10-14 days

Measured Values

	Dalbavancin	Vancomycin With Possible Switch to Oral Linezolid
Participants Analyzed [Units: Participants]	**324**	**302**
Clinical Status [Units: Participants]		
Clinical Succcess	**303**	**280**
Clinical Failure	**21**	**22**

No statistical analysis provided for Clinical Status

3. Secondary: >= 20% Reduction in Lesion Area [Time Frame: 48-72 hours after the initiation of study therapy]

Measure Type	Secondary
Measure Title	>= 20% Reduction in Lesion Area
Measure Description	Clinical response at 48-72 hours post study drug initiation, based on measurements of acute bacterial skin and skin structure infections (ABSSSI) lesion size
Time Frame	48-72 hours after the initiation of study therapy

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

The ITT population consisted of all randomly assigned patients regardless of whether or not they received study drug.

Reporting Groups

	Description
Dalbavancin	IV Dalbavancin: IV Dalbavancin 1000 mg on Day 1 and 500 mg on Day 8
Vancomycin With Possible Switch to Oral Linezolid	Vancomycin/Linezolid: IV Vancomycin (1 gram Q 12 hours or 15mg/Kg Q 12 hours) with optional switch to oral linezolid (600 mg every 12 hours). Total duration of therapy is 10-14 days

Measured Values

	Dalbavancin	Vancomycin With Possible Switch to Oral Linezolid
Participants Analyzed [Units: Participants]	**371**	**368**
>= 20% Reduction in Lesion Area [Units: Participants]		
Clinical Responder	**325**	**316**
Clinical Non-Responder	**46**	**52**

No statistical analysis provided for >= 20% Reduction in Lesion Area

4. Secondary: Clinical Status [Time Frame: Follow-Up Visit (day 28)]

Measure Type	Secondary
Measure Title	Clinical Status
Measure Description	

	Compare the clinical efficacy at the short term follow-up visit of dalbavancin to the comparator regimen based on lesion size, local signs temperature and receipt of other therapy
Time Frame	Follow-Up Visit (day 28)

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Clinical Evaluable Population based on certain inclusion/exclusion criteria, length of study therapy, concomitant antibacterials, concomitant surgical procedure and non-missing data.

Reporting Groups

	Description
Dalbavancin	IV Dalbavancin: IV Dalbavancin 1000 mg on Day 1 and 500 mg on Day 8
Vancomycin With Possible Switch to Oral Linezolid	Vancomycin/Linezolid: IV Vancomycin (1 gram Q 12 hours or 15mg/Kg Q 12 hours) with optional switch to oral linezolid (600 mg every 12 hours). Total duration of therapy is 10-14 days

Measured Values

	Dalbavancin	**Vancomycin With Possible Switch to Oral Linezolid**
Participants Analyzed [Units: Participants]	**294**	**272**
Clinical Status [Units: Participants]		
Clinical Success	**283**	**257**
Clinical Failure	**11**	**15**

No statistical analysis provided for Clinical Status

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Begins from the time that the patient provides informed consent through the last follow up visit, Day 70. Any SAE occurring any time after the reporting period must be promptly reported if a causal relationship to investigational product is suspected.
Additional Description	Adverse events were analyzed in the safety population which is defined as all patients in the ITT population who received at least 1 dose of dalbavancin or vancomycin (active) study drug.

Reporting Groups

	Description
Dalbavancin	IV Dalbavancin: IV Dalbavancin 1000 mg on Day 1 and 500 mg on Day 8
Vancomycin With Possible Switch to Oral Linezolid	Vancomycin/Linezolid: IV Vancomycin (1 gram Q 12 hours or 15mg/Kg Q 12 hours) with optional switch to oral linezolid (600 mg every 12 hours). Total duration of therapy is 10-14 days

Serious Adverse Events

	Dalbavancin	**Vancomycin With Possible Switch to Oral Linezolid**
Total, Serious Adverse Events		
# participants affected / at risk	**12/368 (3.26%)**	**14/367 (3.81%)**
Cardiac disorders		
Cardiac failure congestive [1]		
	1/368 (0.27%)	**0/367 (0.00%)**

# participants affected / at risk		
Cardiopulmonary failure [1]		
# participants affected / at risk	0/368 (0.00%)	1/367 (0.27%)
Gastrointestinal disorders		
Inguinal hernia [1]		
# participants affected / at risk	1/368 (0.27%)	0/367 (0.00%)
Gastrointestinal disorder [1]		
# participants affected / at risk	0/368 (0.00%)	1/367 (0.27%)
Duodenal ulcer perforation [1]		
# participants affected / at risk	0/368 (0.00%)	1/367 (0.27%)
Peritonitis [1]		
# participants affected / at risk	0/368 (0.00%)	1/367 (0.27%)
General disorders		
Systemic inflammatory response syndrome [1]		
# participants affected / at risk	0/368 (0.00%)	1/367 (0.27%)
Sudden death [1]		
# participants affected / at risk	0/368 (0.00%)	1/367 (0.27%)
Hepatobiliary disorders		
Cholecystitis acute [1]		
# participants affected / at risk	0/368 (0.00%)	1/367 (0.27%)
Immune system disorders		
Food allergy [1]		
# participants affected / at risk	1/368 (0.27%)	0/367 (0.00%)

Anaphylactoid reaction [1]		
# participants affected / at risk	**1/368 (0.27%)**	**0/367 (0.00%)**
Infections and infestations		
Abscess [1]		
# participants affected / at risk	**0/368 (0.00%)**	**1/367 (0.27%)**
Cellulitis [1]		
# participants affected / at risk	**3/368 (0.82%)**	**0/367 (0.00%)**
Arthritis bacterial [1]		
# participants affected / at risk	**1/368 (0.27%)**	**0/367 (0.00%)**
Gangrene [1]		
# participants affected / at risk	**0/368 (0.00%)**	**2/367 (0.54%)**
Sepsis [1]		
# participants affected / at risk	**1/368 (0.27%)**	**1/367 (0.27%)**
Necrotising fasciitis [1]		
# participants affected / at risk	**1/368 (0.27%)**	**0/367 (0.00%)**
Bacterial sepsis [1]		
# participants affected / at risk	**0/368 (0.00%)**	**1/367 (0.27%)**
Appendicitis [1]		
# participants affected / at risk	**0/368 (0.00%)**	**1/367 (0.27%)**
Injury, poisoning and procedural complications		
Rib fracture [1]		
# participants affected / at risk	**1/368 (0.27%)**	**0/367 (0.00%)**
Humerus fracture [1]		
	1/368 (0.27%)	**0/367 (0.00%)**

# participants affected / at risk		
Investigations		
Blood glucose increased [1]		
# participants affected / at risk	0/368 (0.00%)	1/367 (0.27%)
Metabolism and nutrition disorders		
Diabetes mellitus inadequate control [1]		
# participants affected / at risk	0/368 (0.00%)	1/367 (0.27%)
Hypokalaemia [1]		
# participants affected / at risk	0/368 (0.00%)	1/367 (0.27%)
Renal and urinary disorders		
Renal failure acute [1]		
# participants affected / at risk	0/368 (0.00%)	1/367 (0.27%)
Respiratory, thoracic and mediastinal disorders		
Pulmonary oedema [1]		
# participants affected / at risk	0/368 (0.00%)	1/367 (0.27%)
Pulmonary embolism [1]		
# participants affected / at risk	1/368 (0.27%)	0/367 (0.00%)
Skin and subcutaneous tissue disorders		
Erythema [1]		
# participants affected / at risk	0/368 (0.00%)	1/367 (0.27%)
Vascular disorders		
Deep vein thrombosis [1]		

# participants affected / at risk	**0/368 (0.00%)**	**1/367 (0.27%)**

1 Term from vocabulary, MedDRA 14.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Begins from the time that the patient provides informed consent through the last follow up visit, Day 70. Any SAE occurring any time after the reporting period must be promptly reported if a causal relationship to investigational product is suspected.
Additional Description	Adverse events were analyzed in the safety population which is defined as all patients in the ITT population who received at least 1 dose of dalbavancin or vancomycin (active) study drug.

Frequency Threshold

Threshold above which other adverse events are reported	2%

Reporting Groups

	Description
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Vancomycin With Possible Switch to Oral Linezolid	Vancomycin/Linezolid: IV Vancomycin (1 gram Q 12 hours or 15mg/Kg Q 12 hours) with optional switch to oral linezolid (600 mg every 12 hours). Total duration of therapy is 10-14 days

Other Adverse Events

	Dalbavancin	

		Vancomycin With Possible Switch to Oral Linezolid
Total, Other (not including serious) Adverse Events		
# participants affected / at risk	**29/368 (7.88%)**	**28/367 (7.63%)**
Gastrointestinal disorders		
Nausea [1]		
# participants affected / at risk	**15/368 (4.08%)**	**15/367 (4.09%)**
Vomiting [1]		
# participants affected / at risk	**8/368 (2.17%)**	**4/367 (1.09%)**
Diarrhoea [1]		
# participants affected / at risk	**4/368 (1.09%)**	**8/367 (2.18%)**
Nervous system disorders		
Headache [1]		
# participants affected / at risk	**11/368 (2.99%)**	**9/367 (2.45%)**

1 Term from vocabulary, MedDRA 14.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

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

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

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** The PI will provide Durata an opportunity to review any proposed publication or other type of disclosure at least 30 days before they are submitted. If any patent action is required to protect intellectual property rights, the Investigator agrees to delay the disclosure for a period not to exceed an additional 60 days. If the study is part of a multi-center study, the Investigator agrees that the first publication is to be a joint publication covering all centers.

Results Point of Contact:

Name/Title: Michael Zelasky
Organization: Durata Therapeutics
phone: 203-871-4616
e-mail: mzelasky@duratatx.com

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

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