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Durata Therapeutics (DRTX - OUTPERFORM): Phase III DISCOVER 1 Trial Meets Endpoint, DISCOVER 2 Up Next, Reiterate OUTPERFORM

Price: \$8.76 12-Month Price Target: \$20

- Durata announced that its Phase III DISCOVER 1 trial of dalbavancin for the treatment of acute bacterial skin and skin structure infections (ABSSSI) had met its primary endpoint of non-inferiority to vancomycin (with the option of switching to linezolid after initial 3-day vancomycin treatment). The non-inferiority margin to meet was 10% at 48-72 hours after therapy started, measured by fever or cessation of lesion speading. The primary endpoint was met by 83.0% of dalbavancin-treated patients and 81.8% of vancomycin/linezolid patients.
- Dalbavancin was well-tolerated, with a lower adverse event rate than vancomycin/linezolid (12.3% vs. 18.3%). Of note, given dalbavancin's long half-life, treatment emergent adverse events after the Day 28 visit were less common in the dalbavancin arm (4.2%) than the comparator (8.5%). Discontinuation rates due to adverse events were also lower in the dalbavancin arm at 1.8% vs. 2.1%.
- We also expect the upcoming DISCOVER 2 Phase III trial to meet its primary endpoint (likely in Q1:13). We continue to
 view dalbanvancin as a de-risked asset, as it had met primary endpoints in three earlier Phase III trials and now the
 DISCOVER 1 trial.
- Regulatory filings could come in mid:13 in both the US and EU. Other catalysts are in the chart below:
 - YE:12 Results of 960 patient first Phase III study of oritavancin (SOLO-1) in the abSSSI setting
 - YE:12 Top line Phase III results for dalbavancin (DISCOVER 1) in the abSSSI setting
 - Q1:13 Top-line Phase III results for dalbavancin (DISCOVER 2) in the abSSSI setting
 - H2:12 Potential completion of enrollment in the second Phase III study of oritavancin (SOLO-2) in the abSSSI setting
 - H2:12 Potential re-partnering transaction for THRX of Vibativ (telavancin)
 - Mid:13 Potential EU MAA filing for dalbavancin in the abSSSI setting
 - Mid:13 Potential US NDA filing for oritavancin in the abSSSI setting with an anticipated 6 month review cycle
 - H1:13 Potential NDA filing with FDA for dalbavancin
- Reiterate OUTPERFORM rating and \$20 price target. Our \$20 share price target is derived from the net present value (25% discount rate) of our estimate of profits and losses for DRTX through our projection of the end of dalbavancin's exclusivity period in the U.S. and EU in 2027 and 2023, respectively, with no terminal value and cash per share in 12 months.
- Risks to our price target include; 1) dalbavancin to demonstrate non-inferiority ongoing Phase III abSSSI clinical trials, 2) commercial and launch risks, 3) regulatory risks and 4) risks to the IP estate of Durata and dalbavancin in the U.S. and ROW.

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Exhibit 1: DISCOVER 1 Endpoint Analysis

DISCOVER 1

Efficacy Analysis: Primary Endpoint

Endpoint	Patient Population	Dalbavancin	Vancomycin / linezolid	Difference (95% Confidence Interval)
Primary (Early Response)	ПТ	239/288 (83.0%)	233/285 (81.8%)	1.2% (-4.9, 7.6)
Sensitivity analysis (>20% reduction in lesion area at 48-72 hours)	ПТ	258/288 (89.6%)	259/285 (90.9%)	-1.3% (-6.1, 3.7)

Source: Company Reports

Exhibit 2: DISCOVER 1 Safety Profile

DISCOVER 1

Safety Assessment

Patients who experienced at least one of:	Dalbavancin (N=284)	Vancomycin/ linezolid (N=284)
Adverse event	113 (39.8%)	117 (41.2%)
Treatment emergent adverse event (TEAE)	99 (34.9%)	112 (39.4%)
TEAE with onset through the SFU (D28) visit	96 (33.8%)	108 (38.0%)
TEAE with onset after the SFU (D28) visit	12 (4.2%)	24 (8.5%)
Drug Related TEAE	35 (12.3%)	52 (18.3%)
Treatment emergent serious adverse events (SAE)	5 (1.8%)	12 (4.2%)
Drug related treatment emergent SAE	0	2 (0.7%)
Treatment emergent SAE leading to death	0	5 (1.8%)
TEAE leading to premature discontinuation (d/c) from drug	5 (1.8%)	6 (2.1%)

Source: Company Reports



Exhibit 3: DISCOVER 1 Adverse Event Profile

DISCOVER 1

Adverse Events

	Dalbavancin (N=284)		Vancomycin/linezolid (N=284)	
	Unrelated	Related	Unrelated	Related
Patients with at least one	61 (21.5%)		56 (19.7%)	
TEAE through SFU (D 28)		35 (12.3%)		52 (18.3%)
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TEAE at \geq 2% in any arm				
Nausea	5 (1.8%)	7 (2.5%)	1 (0.4%)	12 (4.2%)
Diarrhea	2 (0.7%)	2 (0.7%)	2 (0.7%)	9 (3.2%)
Headache	5 (1.8%)	9 (3.2%)	7 (2.5%)	7 (2.5%)
Pruritus	0	1 (0.4%)	2 (0.7%)	9 (3.2%)
Hypertension	7 (2.5%)	0	7 (2.5%)	0
Rash	2 (0.7%)	3 (1.1%)	1 (0.4%)	5 (1.8%)
Asthenia	1 (0.4%)	0	5 (1.8%)	1 (0.4%)

Source: Company Reports



Analyst Certification

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Company	Disclosure
Durata Therapeutics	1,3,4,5,7

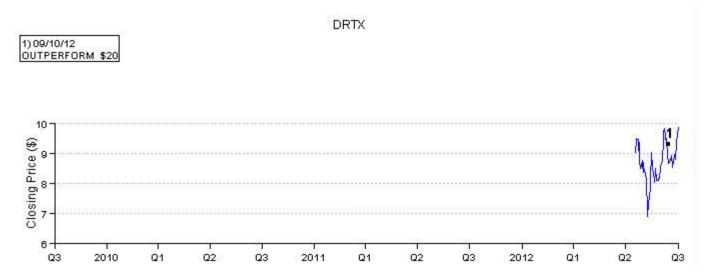
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