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Durata Therapeutics (DRTX - OUTPERFORM): DISCOVER 1 Phase III Meets EMA Required Primary Endpoints, DISCOVER 2 Up Next Q1:13, Reiterate OUTPERFORM

Price: $7.97 **12-Month Price Target: $20**

- **Durata announced that additional analysis of top-line results shows that the Phase III Discover 1 trial of dalbavancin for the treatment of abSSSI met the EMA required primary endpoints (Exhibit 1).** Recall that EMA required primary endpoints include "clinical status" and "investigators' assessment of clinical response". The "clinical status" endpoint measurements include a comparison of clinical efficacy of dalbavancin vs. comparator at end of treatment, based upon lesion size, local signs, temperature and receipt of other therapy at end of treatment visit (Day 14-15). The "investigator assessment of clinical response" includes a day 14-15 assessment of success (dalbavancin vs. comparator), defined as resolution or improvement of all signs and symptoms of infection without treatment-related discontinuation, death, or non-antibacterial intervention for abSSSI (Acute Bacterial Skin and Skin Structure Infections).

- **Dalbavancin was shown to be statistically non-inferior to vancomycin/linezolid in both clinical status and investigator assessments endpoints at the end of treatment.** Dalbavancin resulted in clinical success in 214/246 (87.0%) of all patients compared to 222/243 (91.4%) a -4.4% difference in point estimates, well within the -9.6-1.6, 95% confidence interval (CI). Patient stratification by MRSA showed that dalbavancin resulted in 85.7% vs. 96.8% clinical success (CI not provided).

- **Importantly, we note that under the investigator assessment endpoint, a key variable from a clinical practice and marketing perspective in both the U.S. and EU, dalbavancin stacked up even more favorably vs. vancomycin/linezolid (Exhibit 1).** At the end of treatment, 233/246 (94.7%) of the patients infections were deemed successfully treated by investigators compared to 237/243 (97.5%) a difference of -2.8% again, well within the -6.7-0.7, 95% CI. Additionally, recall that that in previously reported top-line results dalbavancin was well-tolerated with a lower adverse event rate than vancomycin/linezolid (12.3% vs. 18.3%) (Exhibit 4). 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%.

- **Today's data supports our thesis that dalbavancin is a significantly de-risked asset in both the U.S. and now the EU. We also expect the upcoming DISCOVER 2 Phase III trial data, likely in Q1:13, to meet its primary endpoints.** We continue to view dalbavancin as a de-risked asset, as it had met primary endpoints in three earlier Phase III trials and now the DISCOVER 1 trial (Exhibit 2-4).

- **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 the attainment of 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.

Upcoming Milestones

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

Exhibit 1: Top-line Data from the DISCOVER 1 Trial

	Endpoint	Dalbavancin	Vancomycin/ linezolid	Difference in point estimates (95% Confidence interval)
EMA Primary Endpoint	Clinical Status (End of Treatment)	214/246 (87.0%)	222/243 (91.4%)	-4.4% (-9.6, 1.6)*
	Patients with MRSA	30/35 (85.7%)	30/31 (96.8%)	
	Investigator Assessment (End of Treatment)	**233/246 (94.7%)**	**237/243 (97.5%)**	**-2.8% (-6.7, 0.7)**
US Primary Endpoint	Early response (48-72 hours)	240/288 (83.3%)	233/285 (81.8%)	1.5% (-4.6, 7.9)
	Patients with MRSA	37/44 (84.1%)	32/39 (82.1%)	

*adjusted for pre-specified baseline variables.
Source: Company Reports

Exhibit 2: DISCOVER 1 Endpoint Analysis

Endpoint	Patient Population	Dalbavancin	Vancomycin / linezolid	Difference (95% Confidence Interval)
Primary (Early Response)	ITT	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)	ITT	258/288 (89.6%)	259/285 (90.9%)	-1.3% (-6.1, 3.7)

Source: Company Reports

Exhibit 3: DISCOVER 1 Safety Profile

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 4: DISCOVER 1 Adverse Event Profile

	Dalbavancin (N=284)		Vancomycin/linezolid (N=284)	
	Unrelated	Related	Unrelated	Related
Patients with at least one TEAE through SFU (D 28)	61 (21.5%)	35 (12.3%)	56 (19.7%)	52 (18.3%)
TEAE at ≥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

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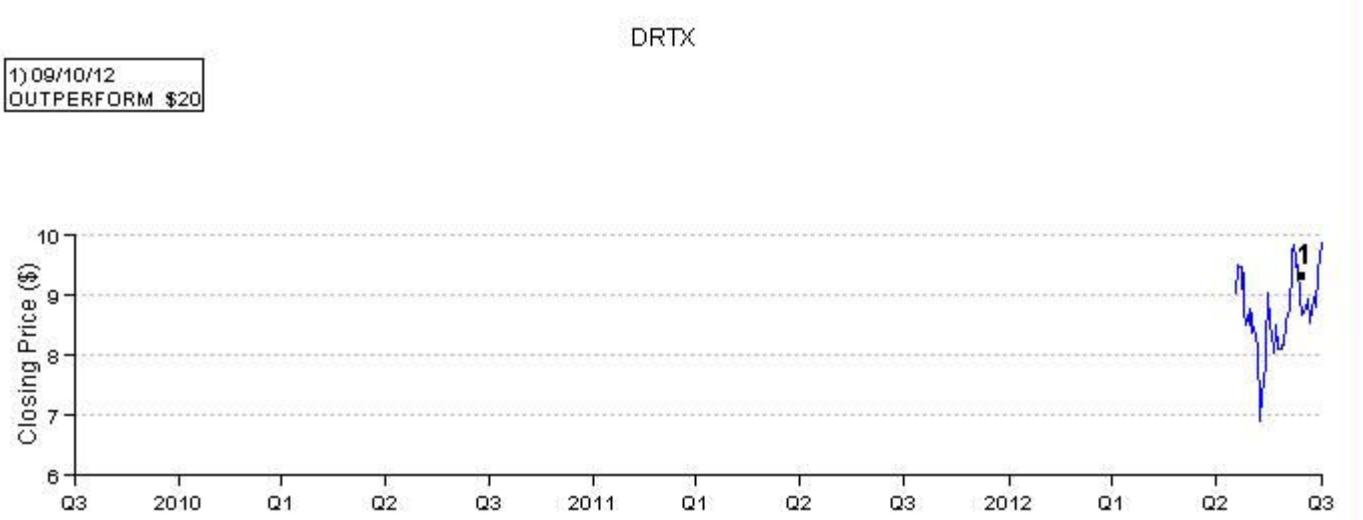

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