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Durata Therapeutics (DRTX - OUTPERFORM): Dalbavancin Continues to Fare Well As Tedizolid Reports Data, Reiterate OUTPERFORM

Price: $8.90 **12-Month Price Target: $26**

- **Trius Therapeutics (TSRX, Not Covered) reported top-line data for its Phase 3, ESTABLISH 2 study of tedizolid in acute bacterial skin and skin structure infections (ABSSSI). This study was a non-inferiority IV to oral transition study versus linezolid (Zyvox, Pfizer: PFE, Not Covered).** Recall that tedizolid is dosed once daily for 6 days and linezolid is dosed twice daily for 10 days.

- **The drugs are not entirely comparable as dalbavancin is a once-weekly infusion, while tedizolid is IV or oral, dosed daily. Key differentiators are cidality (bacterial killing, where dalbavancin is more potent), longer potential duration of therapy (currently tedizolid has not been dosed longer than 21 days) and gastrointestinal tolerability (dalbavancin appears better tolerated).**

- **While the study met its primary endpoint of non-inferiority to linezolid (and was also comparable to Durata's dalbavancin), we note that a top-line review of treatment emergent adverse events (TEAE) seems to favor dalbavancin. Of note, 12.2% of patients with at least one related TEAE were recorded in the DISCOVER 2 trial, whereas 20.5% tedizolid patients in the ESTABLISH 2 trial experienced a drug-related TEAE.**

- **Gastrointestinal side effects were experienced by 4.7% of DISCOVER 2 patients, compared to 16% of tedizolid ESTABLISH 2 patients. Additionally, tedizolid-treated patients showed a discontinuation rate of 5.7% vs 8.4% in the linezolid group. In DRTX's DISCOVER 2 trial, 2.4% of dalbavancin-treated patients prematurely discontinued due to an TEAE.**

- **We continue to view dalbavancin as occupying a unique and important position in the marketplace, particularly in the homecare setting and (off-label) the osteomyelitis setting, where its once-weekly administration carries compliance and administration efficiencies.** We view the homecare market as an especially attractive, relatively price-insensitive where drugs from a known class with a highly favorable administration schedule could take significant share from vancomycin, which can lead to renal toxicity, and is seeing increasing resistance.

- **Reiterate OUTPERFORM rating and $26 price target.** Our $26 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) commercial and launch risks, 3) regulatory risks and 4) risks to the IP estate of Durata and dalbavancin in the US and ROW.

INVESTMENT SUMMARY

Durata's dalbavancin is an intravenous antibiotic in development for the treatment of serious Gram + bacterial infections and if approved, would primarily compete with vancomycin (generic), Cubist's CUBICIN (daptomycin), Forest's Teflaro, and potentially, the Medicines Company's oritavancin. The Company's Phase III clinical studies have been successful and we expect FDA and EMA filings for approval in mid:13 and YE:13, respectively. Dalbavancin's primary potential competitive advantage lies with its infrequent, once weekly administration that should simplify delivery of IV antibiotic therapy in the outpatient setting facilitating care outside of the expensive inpatient settings found in hospitals and skilled nursing facilities. FDA and EMA (European Medicines Agency) NDA (new drug application) and MAA (marketing authorization application) filings are expected in mid:13 and by YE:13 respectively. Uniquely, the drug has been reviewed by FDA with the only outstanding issue remaining the conduct of at least one new Phase III skin clinical study with current, standard efficacy endpoints and non-inferiority margins.

Upcoming Milestones

H2:13 Top line data from the second Phase III study of oritavancin (SOLO-2) in the abSSSI setting
Mid:13 Potential US NDA filing for oritavancin in the abSSSI setting with an anticipated 6 month review
Mid:13 Potential US NDA filing for dalbavancin in the abSSSI setting
H2:13 Potential tedizolid US NDA filing in the abSSSI setting
YE:13 Potential EU MAA filing for dalbavancin in the abSSSI setting
2013 Potential re-partnering transaction for THRX of Vibativ (telavancin)
2014 MDCO launch of oritavancin in the US

Exhibit 1: Top-line Data from DRTX's DISCOVER 1 and 2 Trials

DISCOVER PROGRAM
Efficacy Analysis: Primary Endpoint

Primary Endpoint (Early Response)	Dalbavancin	Vancomycin/ linezolid	Difference (95% Confidence Interval)
DISCOVER 2	285/371 (76.8%)	288/368 (78.3%)	-1.5% (-7.4, 4.6)
DISCOVER 1	240/288 (83.3%)	233/285 (81.8%)	1.5% (-4.6, 7.9)

Sensitivity analysis (>20% reduction in lesion area at 48-72 hours)	Dalbavancin	Vancomycin/ linezolid	Difference (95% Confidence Interval)
DISCOVER 2	325/371 (87.6%)	316/368 (85.9%)	1.7% (-3.2, 6.7)
DISCOVER 1	259/288 (89.9%)	259/285 (90.9%)	-1.0% (-5.7, 4.0)

Source: Company Reports

Exhibit 2: Top-line Data from Tedizolid's ESTABLISH 1 and 2 Trials

Endpoint	Study	Tedizolid 6 days treatment, %	Linezolid 10 days treatment, %	Treatment Difference (95% CI), %
≥20% decrease from baseline in lesion area at 48-72 hours	ESTABLISH 2 ESTABLISH 1	85.2 78.0	82.6 76.1	2.6 (-3.0 to 8.2) 1.9 (-4.5 to 8.3)
Sustained clinical response at end of therapy	ESTABLISH 2 ESTABLISH 1	87.0 87.0	88.0 87.8	-1.0 (-6.1 to 4.1) -0.8 (-5.8 to 4.4)
Investigators assessment of clinical response at 7-14 days after end of therapy	ESTABLISH 2 ESTABLISH 1	88.0 85.5	87.7 86.0	0.3 (-4.8 to 5.3) -0.5 (-5.8 to 4.9)
Cessation of lesion spread and absence of fever at 48-72 hrs	ESTABLISH 2 ESTABLISH 1	85.8 79.5	81.4 79.4	4.4 (-1.2 to 10.1) 0.1 (-6.1 to 6.2)

Source: Company Reports

Exhibit 3: Top-line Safety Data from DRTX's DISCOVER 1 and 2 Trials

DISCOVER 2

Adverse Events

	Dalbavancin (N=368)		Vancomycin/linezolid (N=367)	
	Unrelated	Related	Unrelated	Related
Patients with at least one TEAE [1]	63 (17.1%)		88 (24.0%)	
		45 (12.2%)		37 (10.1%)
TEAE[1] at ≥2% in any arm				
Nausea	6 (1.6%)	9 (2.4%)	8 (2.2%)	7 (1.9%)
Headache	8 (2.2%)	3 (0.8%)	6 (1.6%)	3 (0.8%)
Pruritus	2 (0.5%)	3 (0.8%)	1 (0.3%)	6 (1.6%)
Diarrhea	1 (0.3%)	3 (0.8%)	1 (0.3%)	7 (1.9%)
Vomiting	6 (1.6%)	2 (0.5%)	2 (0.5%)	2 (0.5%)

[1]Through Day 28

Source: Company Reports

Exhibit 4: Top-line Safety Data from Tedizolid's ESTABLISH 1 and 2 Trials

Safety Analysis Set	Study	Tedizolid %	Linezolid %
Any Treatment Emergent Adverse Event (TEAE)	ESTABLISH 2	45.3	43.7
	ESTABLISH 1	40.8	43.3
Any Drug Related TEAE	ESTABLISH 2	20.5	24.8
	ESTABLISH 1	24.2	31.0
Gastrointestinal Disorders	ESTABLISH 2	16.0	20.5
	ESTABLISH 1	16.3	25.4

Source: Company Reports

Analyst Certification
I, Gregory R. Wade, Ph.D., David M. Nierengarten, Ph.D., Christopher N. Marai, Ph.D., certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

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

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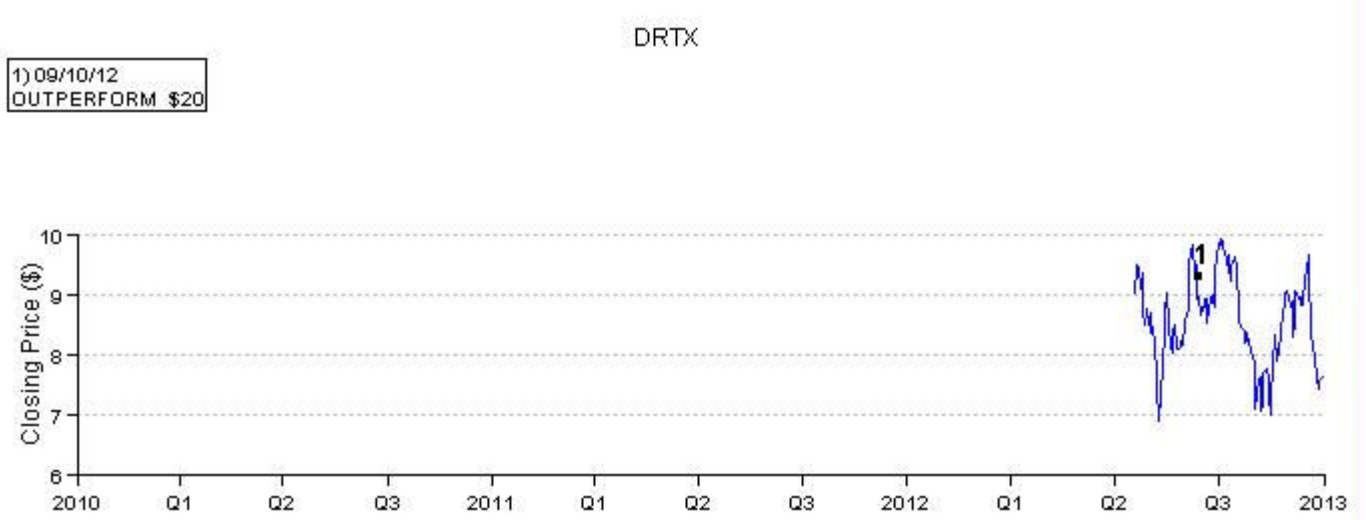

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