



FIRST GLANCE | COMMENT

DECEMBER 21, 2012

Durata Therapeutics, Inc. (NASDAQ: DRTX; 8.46)

DRTX Shares Oversold In Reaction To Oritavancin Data

Outperform Speculative Risk

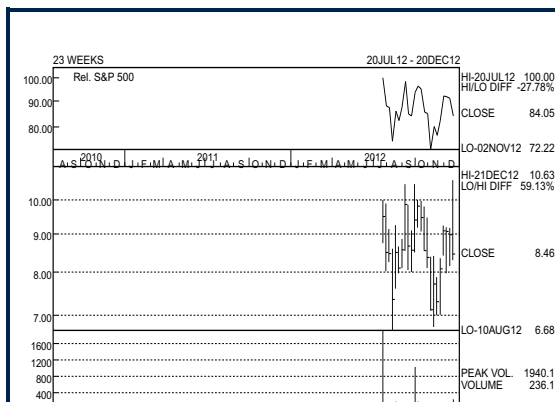
Impact

Neutral - Potential competitor MDCO's oritavancin reported positive Phase III data

First Impression

DRTX shares were weak in response to positive data reported for oritavancin, which met the primary and secondary endpoints in its Phase III study in patients with abSSSI (SOLO-1). We view the sell off as an over-reaction as both DRTX's dalbavancin and MDCO's oritavancin are long-acting antibiotics with sufficiently different clinical attributes that could lead to co-existence in the abSSSI market assuming approval for both. **Key differences include oritavancin being dosed once while dalbavancin is dosed twice weekly. The second major difference is that while dalbavancin is infused over a 30 minute period oritavancin is infused over 3 hours.** Differences are acute enough that both product candidates could find their own niche in a competitive marketplace that is still largely dominated by generic vancomycin.

- **Dalbavancin data from first Phase III study.** The first Phase III trial met its SPA established primary endpoint of non-inferiority to vancomycin (10% margin): 83% of patients receiving dalbavancin vs. 81.8% on vancomycin/linezolid had resolution of fever and stoppage of lesion spread at 48-72 hours (primary endpoint). The subset with at least a 20% reduction in lesion area without fever favored the dalbavancin arm as well. The rate of adverse events, treatment emergent adverse events with onset through day 28 or after day 28, SAEs, etc., were all lower with dalbavancin.
- **Oritavancin data from first Phase III study.** Oritavancin was non-inferior to vancomycin at 48-72 hours in cessation of lesion spread and resolution of fever (10% margin): 82.3% of patients receiving oritavancin vs. 78.9% on vancomycin. Efficacy in patients with microbiologically confirmed MRSA was similar to ITT. Oritavancin was also non-inferior to vancomycin at 7-14 days after end of treatment in curing patients (79.6% vs. 80%). Patients treated with oritavancin appeared to have a similar if not better safety profile than those treated with vancomycin.
- **Next events for dalbavancin and oritavancin.** DRTX will report Phase III data from DISCOVER 2, the larger of the two pivotal studies, in 1Q:13. We also expect several analyses from DISCOVER 1 to shed further light on EU approvability. Data from MDCO's second Phase III study (SOLO-2) is expected around mid-2013. We believe the probability of success for both is high.



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Details

Comparing Dalbavancin and Oritavancin

Oritavancin and dalbavancin are both long-acting lipoglycopeptide antibiotics. These drugs are most similar to vancomycin, which is a so-called glycopeptides antibiotic, but unlike vancomycin which is dosed 2x/day, dalbavancin is dosed once per week (day one and eight) and Oritavancin is dosed in a single administration (day one). Both have the potential to change the way antibiotics are used by providing doctors and hospitals with the ability to treat patients conveniently in the outpatient setting and potentially avoid or reduce hospitalization. Our view is that both drugs can be successful, assuming safety and efficacy results are clean, and that having more than one long-acting antibiotic in the market could help to expand the market, especially as we expect significant marketing efforts could be required to change clinical practice.

- **Mechanism – Similar.** Both dalbavancin and Oritavancin are semi synthetic glycopeptides.
- **Dosing frequency – Different.** Although both dalbavancin and Oritavancin are similar in that they are long-acting antibiotics that allow for infrequent administration, their individual profiles are different. Dalbavancin is dosed twice with a six day interval between doses (day one and eight). Oritavancin could be dosed once.
- **Infusion time – Different.** Dalbavancin is infused over a 30 minute time period. Oritavancin requires a 3 hour infusion. Given that the three hour infusion is what is being used in the Phase III studies, it is unlikely that a shift to a shorter regimen could occur even if it were clinically feasible at this juncture.
- **Safety – Similar.** Neither of the Phase III studies reported so far showed a safety concern.
- **Efficacy – Similar.** Both Phase III studies reported so far met their primary endpoint of non-inferiority to vancomycin. Outcomes around secondary endpoints are less clear as DRTX is still analyzing data and expect to update the Street in 1Q:13.
- **Efficacy in patients with MRSA – Likely similar.** However, we await further details
- **Treatment settings – Likely different.** Dalbavancin appears to be an ideal candidate for the Emergency Room setting with a 30 minute infusion. Oritavancin's three hour infusion time could be more challenging; however, it could also be suitable in settings such as in-patient or home healthcare.
- **Cost savings – Likely similar.** We believe both dalbavancin and oritavancin could make similar arguments in terms of costs savings to the system with a focus on either reducing in-patient costs by reducing admissions or expediting discharges or reducing out-patient costs by eliminating the need for infusions.
- **Price – Likely similar.** We expect both dalbavancin and oritavancin to be priced similarly and in-line with where branded products are priced.

Phase III Data from DRTX's DISCOVER 1 Study

Phase III DISCOVER 1 Top-Line Efficacy

Endpoint	Patient Population	Dalbavancin	Vancomycin /		Difference		
			linezolid		(95% Confidence Interval)	Absolute Difference	
Primary (early response)	ITT	239 / 288	83.0%	233 / 285	81.8%	1.2% (-4.9, +7.6)	1.2%
>20% reduction in lesion area at 48-72 hrs	ITT	258 / 288	89.6%	259 / 285	90.9%	-1.3% (-6.1, +3.7)	-1.3%
Secondary Endpoints							
Clinical status at EOT (day 14-15)	CE*	214 / 246	87.0%	222 / 243	91.4%		-4.4%
	ITT	236 / 288	81.9%	247 / 285	86.7%		-4.7%
Investigator assessment at EOT (day 14-15)	CE	233 / 246	94.7%	237 / 243	97.5%		-2.8%
	ITT	260 / 288	90.3%	262 / 285	91.9%		-1.7%
Clinical status at SFU (day 28)	CE	212 / 226	93.8%	220 / 229	96.1%		-2.3%
	ITT	241 / 288	83.7%	251 / 285	88.1%		-4.4%
Investigator assessment at SFU (day 28)	CE	213 / 226	94.2%	223 / 229	97.4%		-3.1%
	ITT	248 / 288	86.1%	255 / 285	89.5%		-3.4%

*EMA primary endpoint.

Source: Company reports.

Phase III DISCOVER 1 Top-Line Safety

	Dalbavancin	Vancomycin / linezolid
N	284	284
Adverse events	39.8%	41.2%
Treatment emergent adverse events	34.9%	39.4%
TEAE with onset through D28 visit	33.8%	38.0%
TEAE with onset after D28 visit	4.2%	8.5%
Drug related TEAE	12.3%	18.3%
TESAE	1.8%	4.2%
Drug related SAE	0.0%	0.7%
TESAE leading to death	0.0%	1.8%
TEAE leading to discontinuation	1.8%	2.1%

	Unrelated	Related	Unrelated	Related
Patients with at least one TEAE through D28	21.5%	12.3%	19.7%	18.3%
TEAE at >= 2% in any arm				
Nausea	1.8%	2.5%	0.4%	4.2%
Diarrhea	0.7%	0.7%	0.7%	3.2%
Headache	1.8%	3.2%	2.5%	2.5%
Pruritis	0.0%	0.0%	0.7%	3.2%
Hypertension	2.5%	0.0%	2.5%	0.0%
Rash	0.7%	1.1%	0.4%	1.8%
Asthenia	0.4%	0.0%	1.8%	0.4%

Source: Company reports.

Phase III data from MDCO's SOLO 1 Study

SOLO-1 Phase III Efficacy and Safety Data

	Oritavancin		Vancomycin		% Difference
N	475		479		
Efficacy					
Primary endpoint (48-72 hours)					
Cessation of lesion spread, absence of fever, no rescue antibiotics	391	82.3%	378	78.9%	3.4% (-1.6, +8.4)
>= 20% reduction of lesion area	413	86.9%	397	82.9%	4.1% (-0.5, +8.6)
Secondary endpoint (7-14 days)					
Investigator assessed clinical cure	378	79.6%	383	80.0%	-0.4% (-5.5, +4.7)
Patients with confirmed MRSA infections:					
N	104		100		
Primary endpoint (48-72 hours)					
Cessation of lesion spread, absence of fever, no rescue antibiotics	84	80.8%	84	84.0%	
>= 20% reduction of lesion area	94	90.4%	84	84.0%	
Secondary endpoint (7-14 days)					
Investigator assessed clinical cure	86	82.7%	83	83.0%	
Safety					
At least 1 AE	60.0%		63.8%		
TEAE	22.8%		31.4%		0.003
Skin and subcutaneous tissue adverse events	11.6%		19.1%		0.001
Phlebitis	Similar in both arms				

Source: Company reports.

Company Description

Durata Therapeutics is focused on the development and commercialization of novel therapeutics for patients with infectious diseases and acute illnesses. Enrollment in two global Phase III clinical trials with Dalbavancin, DRTX's primary value driver, for the treatment of acute bacterial skin and skin structure infections (abSSSI) is ongoing and results are expected in YE:12 from the first study and early 2012 from the second study. Dalbavancin is an intravenous antibiotic product candidate designed for once-weekly dosing, which differentiates from currently marketed antibiotics and increase the convenience of treating patients in the out-patient and in-patient settings, while lowering the overall cost of care to the healthcare system. Assuming a positive outcome, Durata will submit an NDA to the FDA in 1H:13 and an MAA to the EMA in 2H:13. Currently, the company plans to commercialize Dalbavancin directly in the US and EU with a targeted hospital sales force.

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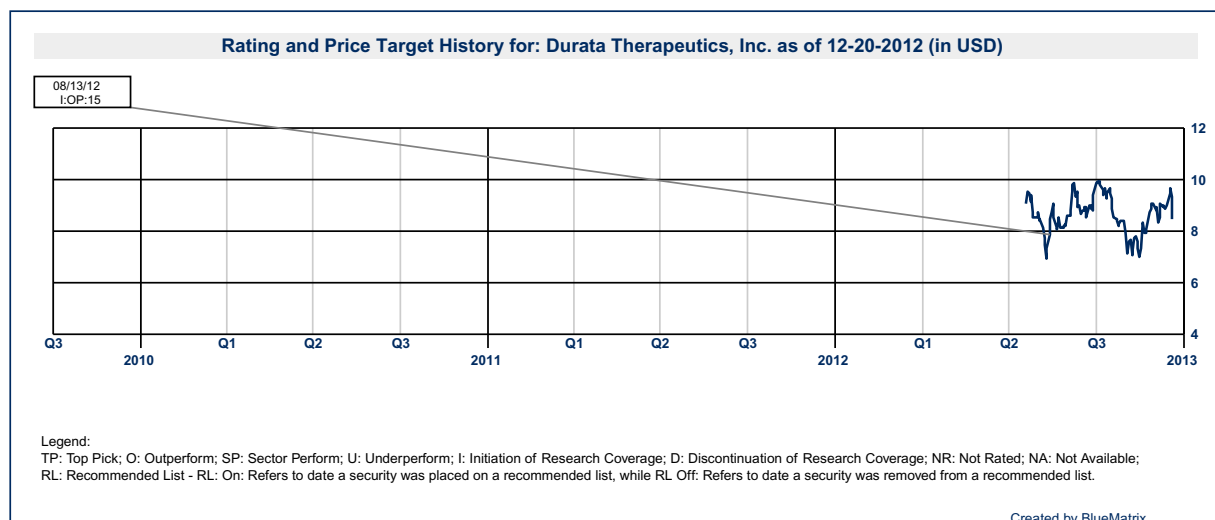
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