



FIRST GLANCE | COMMENT

JANUARY 4, 2013

Durata Therapeutics, Inc. (NASDAQ: DRTX; 8.11)

Dalbavancin Met Endpoint Required For EU Approval

Outperform Speculative Risk

Impact

Positive - Updated DISCOVER-1 analysis shows dalbavancin met the cure endpoint required to file MAA

First Impression

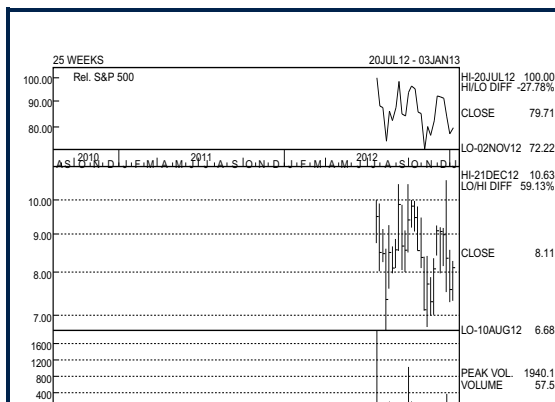
DRTX previously reported positive data from its first Phase III study of dalbavancin but shares came under pressure when investors questioned whether a regulatory filing in EU would be possible or not. Updated analysis from DISCOVER-1 shows that dalbavancin met the 10% non-inferiority margin for the cure endpoint needed to file for approval in the EU and should address this overhang. Next steps would be Phase III results from the second pivotal study in 1Q:13 followed by NDA and MAA filings although theoretically DRTX could file the NDA using Study VER001-9 and DISCOVER 1 data.

• What's new or updated from DISCOVER 1?

1. The secondary endpoint, clinical status at end of treatment (day 14-15) met the non-inferiority margin of 10% with 87% of patients on dalbavancin cured and 91.4% in the comparator arm [-4.4% (-9.6, +1.6)]. The adjustments made were pre-specified and part of the statistical analysis plan for the dalbavancin studies.
2. The primary endpoint, which already met the SPA established non-inferiority margin of 10% to vancomycin, was updated to show a difference of +1.5% (-4.6, +7.9) from +1.25 previously.
3. DRTX also broke out outcomes in MRSA patients, which appear largely comparable. We do not believe DRTX was asked to enroll any specific number of MRSA patients in the DISCOVER studies.

• **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. This will be followed by an NDA filing in mid-2013 and an MAA filing by YE:2013. We believe the probability of success is high with a US approval expected in 2014.

• **Expectations for DISCOVER 2.** Based on outcomes of the DISCOVER 1 study we believe DISCOVER 2 data should be positive as well, which could fully de-risk DRTX shares from a clinical risk perspective. The trials are identical in design, however, DISCOVER 2 was upsized to maintain the 90% power calculation and should have enrolled ~740 patients. The DISCOVER program compares dalbavancin to vancomycin in two Phase III studies. The primary endpoint is cessation of lesion spread and absence of fever at 48-72 hours with a non-inferiority margin of 10%. The secondary endpoint is clinical status at end of treatment visit (day 14-15).



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Details

Phase III Data from DRTX's DISCOVER 1 Study

Phase III DISCOVER 1 Top-Line Efficacy

Endpoint	Patient Population	Dalbavancin		Vancomycin / linezolid		Difference (95% Confidence Interval)	Absolute Difference	Comment
Primary (early response)	ITT	240 / 288	83.3%	233 / 285	81.8%	1.5% (-4.6, +7.9)	1.6%	Updated
>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%	
Patients with MRSA		37 / 44	84.1%	32 / 39	82.1%			New
Secondary Endpoints								
Clinical status at EOT (day 14-15)*	CE*	214 / 246	87.0%	222 / 243	91.4%	-4.4% (-9.6, +1.6)**	-4.4%	New
	ITT	236 / 288	81.9%	247 / 285	86.7%		-4.7%	
Patients with MRSA		30 / 35	85.7%	30 / 31	96.8%			New
Investigator assessment at EOT (day 14-15)	CE	233 / 246	94.7%	237 / 243	97.5%	-2.8% (-6.7, 0.7)	-2.8%	New
	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. **Adjusted for pre-specified baseline variables.

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.

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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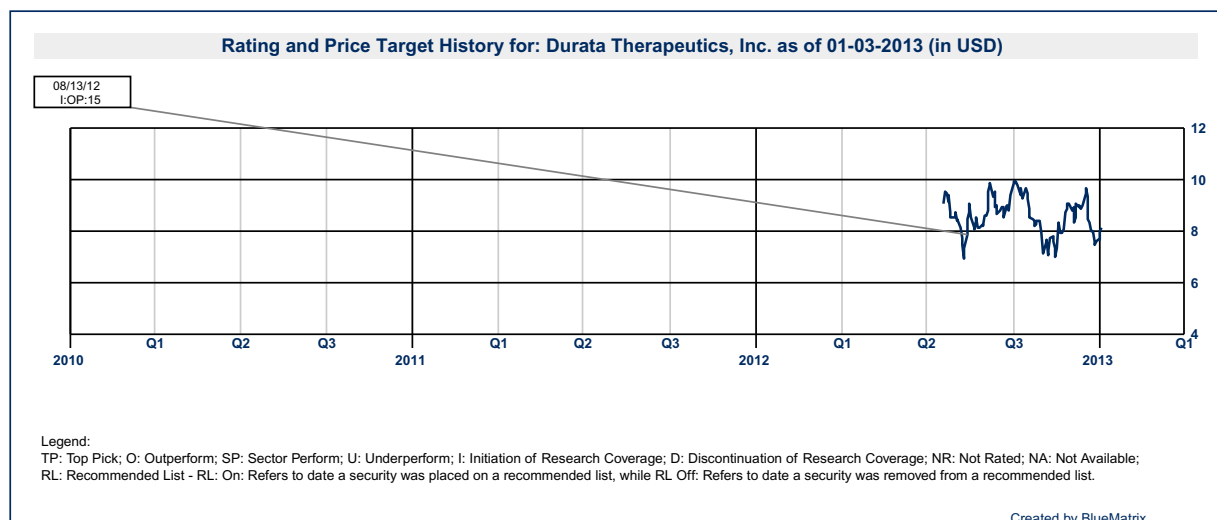
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