



FIRST GLANCE | COMMENT

DECEMBER 13, 2011

Endocyte, Inc. (NASDAQ: ECYT; 10.29)

Independent Review Raises New Concerns

Outperform Speculative Risk

Impact

Negative - Hazard ratios and OS benefit decrease in subsequent analysis. Phase III design may need adjustment

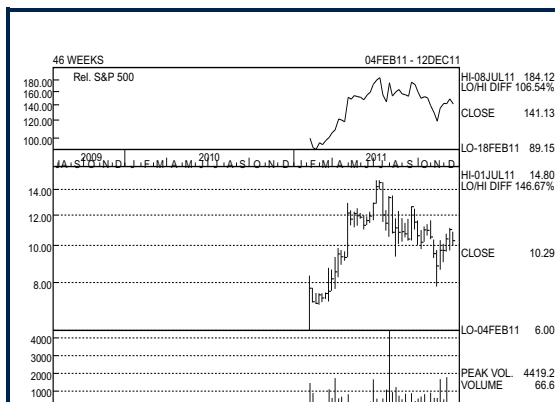
First Impression

The independent review and updated overall survival data show a decrease in benefit relative to the original analysis. Specifically, ECYT is now only reporting a statistically significant PFS benefit in the FR(++) group and the median OS now surprisingly favors the control arm (though the hazard ratio shows that they are essentially the same). We believe these results increase clinical and timing risk for the Phase III and regulatory risk in Europe.

- **The good news.** Concordance in reading the EC20 assay was high with 87% agreement on FR(+) patients and 85% agreement on FR(++) patients. This high concordance rate suggests that this analysis can be implemented in the Phase III and subsequently in clinical practice.
- **The bad news.** Statistical significance of the PFS benefit was lost in the overall population (retained in the FR++ patients). Importantly, all signs of an overall survival benefit were lost with additional follow up. The HR for OS was 1.099 and the median OS actually favored the control group at 16.9 months vs. 14.1 months. ECYT cites more post treatment platinum therapy and better prognostic factors at baseline that could have confounded the results.
- **Next steps in EU.** ECYT will need to discuss these new results with consultants and regulators before filing for EU approval. We continue to expect ECYT to file based on PFS in the FR(++) group.
- **May see changes to Phase III protocol.** ECYT may seek to amend the protocol to (1) only include FR(++) patients, (2) randomize 1:1 to get more patients on the control arm for better statistical comparison, and (3) pre-stratify based on platinum-free interval, which was a prognostic factor that impacted OS in the Phase II. Given the trial is essentially on hold due to the Doxil shortage, these changes may be possible. However, the timing and clinical risk are increased.
- **Some nuance to the new progression data.** There was a reasonably high 74% rate of agreement in calling progression between investigator and independent review. Unfortunately, and not well described ahead of time, patients in the control arm mostly progressed on the first scan, so an independent review could not compress that further. For disagreements on the treatment arm, progression could be called earlier or patients could be censored, but a lack of post progression scans made a later determination impossible. Therefore these results were biased toward compression of benefit.

Priced as of prior trading day's market close, EST (unless otherwise noted).

For Required Conflicts Disclosures, see Page 4.



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All values in USD unless otherwise noted.

Details

Original and Re-Analysis of the Phase II PFS Data

EC20 subset	Hazard ratio	p value	Comments
++	0.381	0.018	Co-primary subset in Phase III
+/++	0.547	NR	Co-primary subset in Phase III
-/+ / ++	0.626	0.031	Primary analysis in Phase II
+	0.87	NR	
-	1.8	0.5	Excluded from Phase III
Approximate breakdown			
++	40%		
+	40%		
-	20%		

Re-read of the scans	
Hazard ratio	p value
0.465	0.0498
0.652	ns
0.768	ns

Source: Company reports

Key News Flow

Timing	Expected News Flow	Program
Q1:12	Initiate Phase II trial in NSCLC	EC145
Q1:12	Final Phase II overall survival data from PRECEDENT	EC145
Q1:12	PFS results of independent scan reads for Phase II PRECEDENT	EC145 / EC20
Q1:12	Results of concordance study for EC20	EC20
Q1:12	MAA filing for ovarian cancer	EC145 / EC20
H1:12	Initiate new clinical program	Pipeline
2012	Potential partner for EC145	EC145
Q2:13	Final Phase III PFS results from PROCEED; interim OS results	EC145
2013	Approval and launch in EU	EC145 / EC20
Q3:13	Final PFS data in NSCLC	EC145
Late 2015/early 2016	Final Phase III PFS results from PROCEED; interim OS results	EC145

Source: Company reports and RBC Capital Markets estimates.

Products And Pipeline

Product	Indication	Target	Payload	Status
Cancer				
EC145	Platinum resistant ovarian cancer	FR	DAVLBH	Phase III
	Non-small cell lung cancer		DAVLBH	Phase II
EC0489	Solid tumors	FR	DAVLBH	Phase I
EC0225	Solid tumors	FR	DAVLBH / Mitomycin-C	Phase I
EC17	Solid tumors	FR	Hapten	Phase I
EC0531	Solid tumors	FR	Tubulysin-B	Preclinical
EC1069	Prostate cancer	PSMA	Tubulysin-B	Preclinical
Inflammation				
ECO746	Inflammation	FR	Aminopterin	Preclinical
ECO565	Inflammation	FR	mTor inhibitor	Preclinical
Companion Imaging Diagnostics				
EC20	Diagnostic (folate receptor)	FR	Tc-99m	Phase III
EC0652	Diagnostic (prostate)	PSMA	Tc-99m	Phase I

Source: Company reports and RBC Capital Markets.

Company Description

Endocyte is a biopharmaceutical company developing targeted therapies for the treatment of cancer and other serious diseases. The company uses its proprietary technology to create novel small molecule drug conjugates (SMDCs) and companion imaging diagnostics. SMDCs actively target receptors that are over-expressed on diseased cells, relative to healthy cells, which enables the treatment of patients with highly active drugs at greater doses, delivered more frequently, and over longer periods of time than would be possible with the untargeted drug alone. The combination of an SMDC with its companion imaging diagnostic is designed to personalize the treatment of patients by delivering effective therapy, selectively to diseased cells, in patients most likely to benefit. The company's lead SMDC, EC145, targets the folate receptor, which is frequently over-expressed in some of the most prevalent, and difficult to treat solid tumor indications, including ovarian, non-small cell lung, breast, colorectal, kidney, endometrial, and other cancers.

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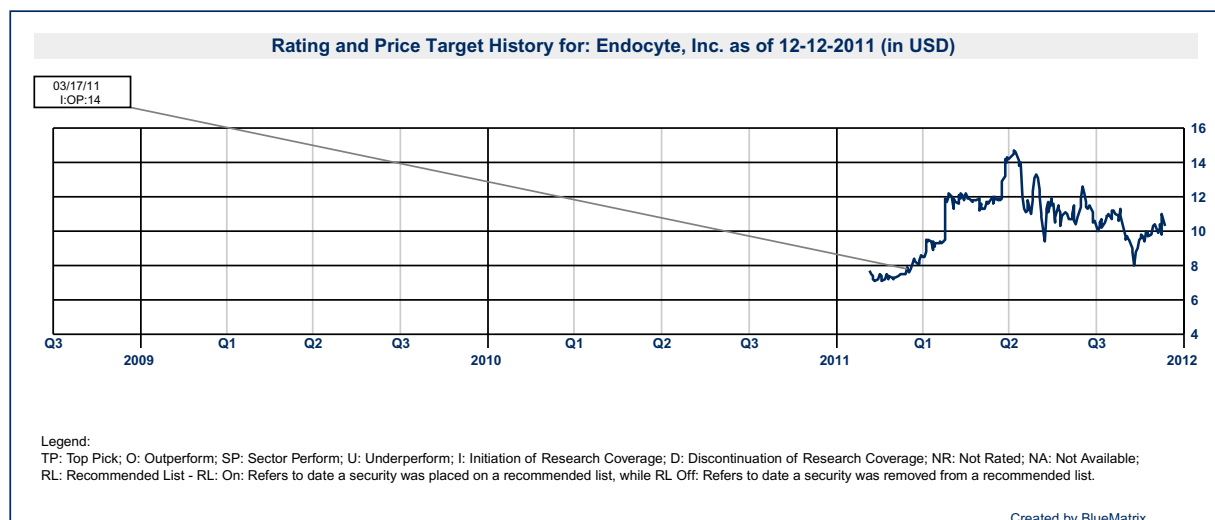
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