

Quick Take

Endocyte — **Outperform** (1)

ECYT: \$3.98

Quick Take: Sell-off overdone; EC145 still a safe drug with real PFS benefit

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Endocyte held a conference call this morning providing supplemental analyses from the Phase II PRECEDENT trial in ovarian cancer with EC145. The market has reacted very negatively on the news, with the stock currently trading around \$3.85/share, only slightly above the cash position of \$3.25/share, assigning very minimal value to EC145.

We believe that given:

- 1) the delays implicit in the news driven by the lack of resolution in the Doxil shortage issue, and
- **2)** the fact that the Overall Survival data *at first glance* point to an apparent degradation in O/S versus placebo, justify the market's reaction, *but only up to a point*. We strongly believe that the market has overreacted and current levels present a very attractive buying opportunity, even in the short-term.

We reiterate our Outperform rating and see significant upside from current levels, especially given the fact that today's data confirm the compound's very impressive PFS benefit (4 months vs. 1.5 months, EC145+Doxil vs. Doxil alone) and its potential for approval, at least ex-US.

The main news out of the call were:

1) The Doxil shortage issue remains unresolved, with no time horizon for the enrollment of new patients in the PROCEED Phase III trial, and the company now seriously considering a second Phase III trial using the combination of EC145 with weekly paclitaxel vs. paclitaxel alone. Finalizing these plans, getting the buy-in of FDA and EMA and getting a second trial up and running will definitely take more time, so the Doxil issue continues to cause problems for ECYT by causing additional delays. The company is considering conducting the Phase III program in FR++ patients alone, in which the PFS benefit is very significant, which may translate in two smaller Phase III studies, approximately equivalent in size with the one large Phase III study which would have included both FR++ and FR+ patients. A potential advantage here is that the company may be able file an NDA on the basis of two studies instead of one, which could make for a stronger regulatory filing, despite the delay in filing.

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2) The Overall Survival data came in and was worse than what we had anticipated (14.1 months vs. 16.9 months, EC145+PLD vs. PLD alone), which at first glance looks very bad. However, a couple of subtle points make us much less bearish than the current market reaction. A) The O/S observed in the Doxil alone arm (~17 months) is much higher than any observed O/S results in recent trials, which are in the 12-13 month range. B) Given that this was a small trial that was 2:1 randomized EC145+Doxil vs. Doxil alone, we are dealing with a very small number of patients in the Doxil alone arm, so it is inherently risky to draw strong conclusions from such a sample size one way or another. Finally, the hazard ratio of slightly above 1.0 points not to a degradation of O/S, but at worst case, to no effect on O/S, which again, given the small sample size, we believe it would be unwise to conclude that EC145 will not have an effect in O/S in the Phase III setting.

While we acknowledge that today's news (delays in regulatory filings in the EU and US, and lack of clarity on the O/S effect), create additional overhangs in the stock, we view current share price levels as very low and as presenting a very attractive entry point into the stock. We reiterate our Outperform rating on ECYT on our belief that EC145 is a safe drug with a real PFS benefit in an indication with special sensitivities (i.e. women) with a significant unmet medical need.

More detail on the data presented on today's call:

PFS efficacy data: There was a 2.5-month or 166% improvement in the median PFS for FR (++) patients in the trial that received EC145 and PLD (4.0 months vs. 1.5 months), which was statistically significant (p=0.0498) with a hazard ratio of 0.465. A similar improvement of 2.5 months or 166% was also observed in FR(+) patient population. However, the improvement was not statistically significant in this broader group. Of note the PFS improvement, by investigator assessment previously presented at the 2011 ASCO, was 4.2 months or 263% in FR(++) patients and 4 months or 225% in FR(+) patients.

Overall Survival efficacy data: The PRECEDENT trial was not powered to show an improvement in O/S and the results did not show O/S benefit in the patients treated with EC145. Median O/S in the treatment arm was 14.1 months compared to 16.9 months in the control arm. Management pointed to the fact that patients in the control arm received more post study platinum based chemotherapy (33% vs. 18%), which could have resulted in increased O/S in the control group.

EC20 validated: The evaluation of the EC20 images, by the independent readers, from the PRECEDENT trial showed a 87% agreement rate in selecting patients with at least one tumor positive for folate-receptor, FR(+) and an 85% agreement rate in selecting patients with all folate-receptor positive tumors, FR(++).



Addendum

STOCKS MENTIONED IN IMPORTANT DISCLOSURES

Ticker	Company Name	
ECYT	Endocyte	

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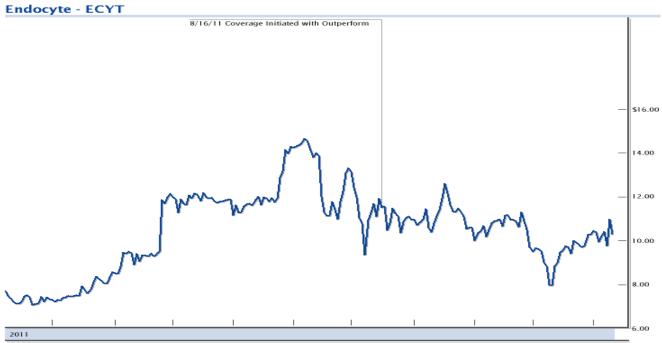
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