

Stemline Therapeutics (STML)

Positive Update As More Lymphoma Patients Are Treated With SL-401

Key Takeaway

We learned that four new patients have been treated in the Phase 2 trial of SL-401 for BPDCN, a rare lymphoma, bringing the total treated to 12 with BPDCN. Although final audited data are not available, we believe that three of the four patients have tolerated therapy well and have responded or are predicted by the treating investigator to likely turn into an objective response. One of the three patients is also scheduled for retreatment later this week.

SL-401 Poster In Line With Expectations. The poster at ASH contained only incremental new data: 5 of the 7 evaluable patients have achieved a complete response, and there were two complete responses still ongoing at the time of the data cutoff (14+ months and 4+ months), which we believe occurred over the summer. Based on the latest update from the investigator, we believe that these two patients continue in remission at 16+ months and 6-7+ months at this time, respectively. The investigator noted that this should be seen as a major breakthrough given the short life expectancy of BPDCN patients (12 months in relapsed/refractory disease).

Four New Patients Treated: Strong Efficacy Consistent With Prior Data. Since the time of the data analysis for the poster, we learned that four additional patients have been treated. One patient achieved a response after just a single dose of SL-401 (a full cycle of therapy consists of 5 doses, once per day for 5 days), but he was not given further drug due to an underlying cardiovascular condition. Specifically, this patient entered the trial with pre-existing heart failure. We do not believe that SL-401 exacerbated his heart failure, but drug was suspended to ensure that treatment was safe. This patient has been in response for one month and we believe his response is still ongoing. Follow-up on the next two patients is immature, but the treating investigator characterized one patient as being on his way to a complete response shortly, and one patient as “doing well” but follow-up is still too early. The fourth patient treated did not fare well on SL-401 and died in the week following treatment, but this appears related to rapidly progressing underlying disease rather than a drug-specific toxicity. Details on the patient’s baseline demographics are still being collected and audited, but we understand that the patient arrived for treatment with much more advanced disease than the referring physician had indicated and had over 90% blast cells in the marrow and calcium levels already at 12mg/dL. On the morning of his first dose, the patient’s calcium levels had risen to 13 mg/dL pre-treatment and was 15mg/dL by the afternoon. We believe that this patient’s first dose was stopped prematurely, and we believe that this patient’s poor baseline health confounds interpretation of efficacy or safety data. With three of four patients likely to respond in this latest cohort, we see the new data as confirmatory of the early BPDCN efficacy signals.

Third Retreatment Likely To Occur Later This Week. We have also learned that the first new patient described above, the one who responded after only a single dose of drug and whose response has lasted for a month to date, is now scheduled for retreatment with SL-401 later this week. The data from this patient could be more informative of the efficacy and safety of retreatment than the two prior retreated patients because of the short one-month interval between his first dose and this upcoming retreatment cycle. This more closely mirrors the proposed regimen of every-three-week cycles to be implemented in the pivotal trials. That said, even this patient’s retreatment data will be difficult to interpret and extrapolate since he received only one dose previously, and thus, this upcoming retreatment cycle could also be seen as a continuation of his first cycle. Thus, the true test of the safety and efficacy of multiple cycles will come with the initiation of the pivotal trials in BPDCN, expected in mid-2014.

BUY

Price target \$60.00

Price \$21.34

Thomas Wei *
Equity Analyst

(212) 284-2326 twei@jefferies.com

Rebecca Forest *

Equity Associate

(212) 284-2170 rforest@jefferies.com

Timothy Chou *

Equity Associate

(212) 284-2571 tchou@jefferies.com

Shaunak Deepak *

Equity Associate

(212) 284-2020 sdeepak@jefferies.com

* Jefferies LLC

Company Description

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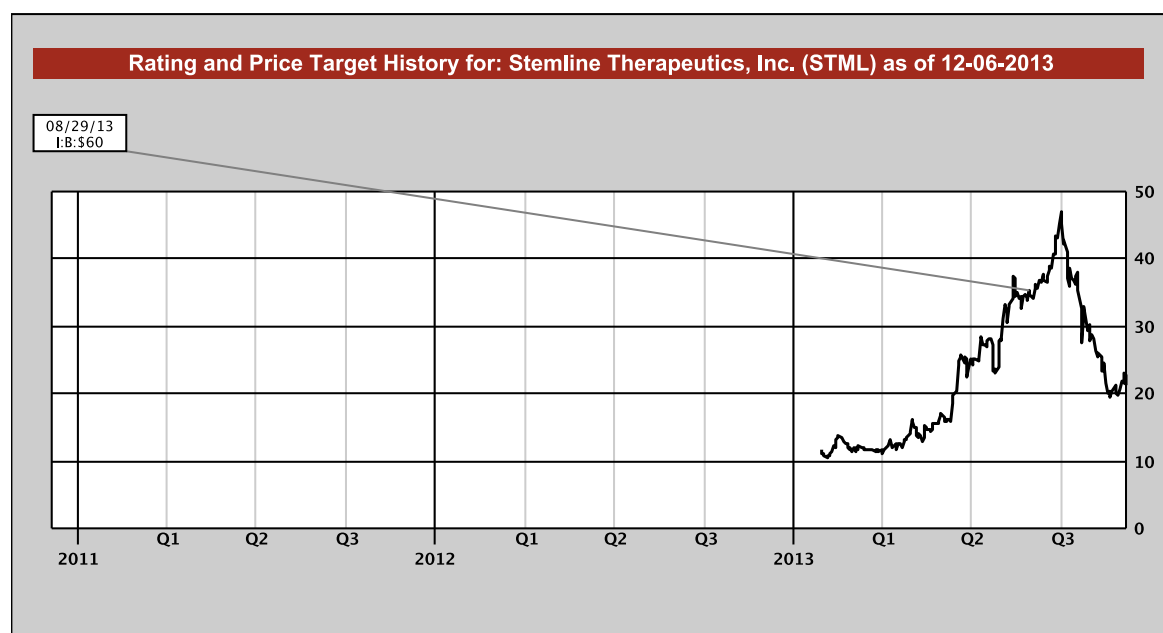
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			Count	Percent
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