

Stemline Therapeutics (STML) Update On SL-401 Retreatment In Advance Of ASH Presentations

Key Takeaway

STML announced that the first BPDCN patient retreated with SL-401 had a clearance of skin lesions and did not experience a dose-limiting toxicity. The primary goal of retreatment is to demonstrate the safety of a second cycle of therapy, and thus, we are very positive on the favorable tolerability profile of this initial retreatment ahead of the pivotal trials, which will incorporate multiple cycles of SL-401.

First SL-401 Retreatment Appears Safe. STML provided initial commentary on the first patient with blastic plasmacytoid dendritic cell neoplasm (BPDCN), a rare lymphoma, who has received a second cycle of SL-401. Specifically, one patient was retreated with SL-401 after relapsing from a previous 3-month complete response (CR), and experienced clearance of skin lesions within the first 2-3 days of treatment but had eventual disease progression in bone marrow that prevented him from achieving an objective response. Most importantly, no notable adverse events occurred, with no Grade 3 toxicity in this retreatment cycle (this patient likewise did not experience a Grade 3 toxicity in his first cycle). Although early and limited to a single patient, we are very encouraged by the safety of SL-401 retreatment. In particular, the key toxicities to monitor are capillary leak syndrome (CLS) and liver enzyme elevations. As a reminder, a key part of our thesis on STML has been that multiple cycles of SL-401 would have the potential to improve efficacy without a dangerous increase in these side effects. From an efficacy standpoint, we are not overly concerned about the lack of an objective response in this patient, as retreatment in the context of this study was suboptimal. The retreated patient had only received one cycle previously, had been off drug for months, had a two month interval between relapsing from his initial SL-401 complete response and the start of retreatment, and had highly progressive disease.

STML Intends To Include Multiple Cycles Of SL-401 In Pivotal Trials. We expect a pivotal trial in BPDCN to begin in 1H14, and unlike the retreatment protocol above, STML will evaluate a dose of 12mcg/kg given IV for five days every three weeks. Following six of these three-week cycles of SL-401, patients will be assessed for adverse events for potential treatment to progression. Given the safety profile seen in the retreated patient above, we are optimistic about an improved risk-benefit with multiple cycles.

Another New CR Observed In BPDCN Trial. STML noted that two new BPDCN patients have been dosed with SL-401 and the one evaluable patient has experienced a complete response, bringing the total to five CRs and one partial response (PR) among the seven evaluable patients. We note that among previously reported objective responses, durations were variable and in-line with the data from ASCO with the CRs at 13+ (ongoing, 11+mo in abstract), 5, 3, and 1 months, and the PR at 1 month. We continue to see these single treatment cycle BPDCN data as highly promising.

Side Effect Update In Line With Expectations. We had previously noted that the recent ASH meeting abstract for BPDCN contains information on new Grade 3 adverse events (transient liver enzyme elevations, transient myelosuppression) that were not disclosed during the ASCO presentation in June. As this is an investigator sponsored study and STML has limited input into medical meeting presentations, we believe a full report on side effects may have lagged and was not available at ASCO as the trial was still (and is still) in progress. We would highlight that these Grade 3 side effects were all transient and asymptomatic, and more importantly, these were entirely consistent with the safety database for SL-401 across all indications. We are also encouraged that similar signals arose in the development of Ontak, a related biologic-toxin conjugate for lymphoma, but did not lead to any major adverse clinical consequences.

BUY

Price target \$60.00

Price \$24.55

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Company Description

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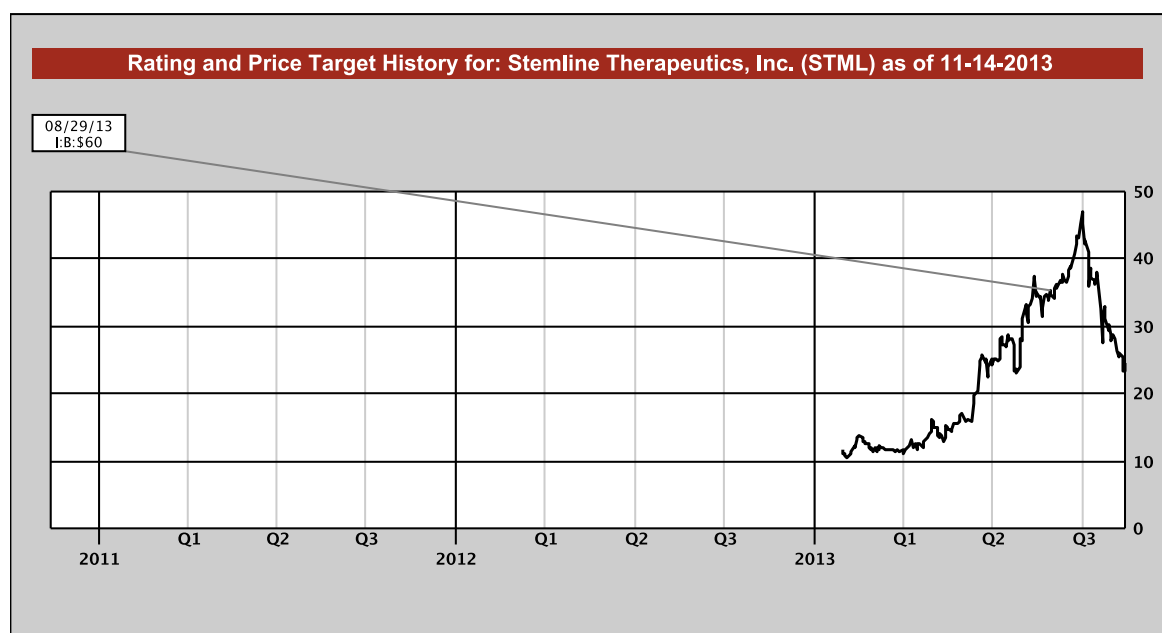
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