

Stemline Therapeutics (STML)

Second Retreatment With SL-401 Supports Safety Of Multiple Cycles

Key Takeaway

We are aware of a second BPDCN patient retreated with SL-401 who tolerated the therapy but did not achieve a response. That said, the primary goal of retreatment is to demonstrate the safety of a second cycle of therapy, as there was a significant lapse between cycles. Thus, we remain positive on the favorable tolerability profile of multi-cycle therapy in the pivotal trials to start in 1H14.

Second Retreatment With SL-401 Was Safe – No Response Observed. A second patient with blastic plasmacytoid dendritic cell neoplasm (BPDCN), a rare lymphoma, has been retreated with SL-401 in November 2013 following an initial cycle of SL-401 in August 2012 that resulted in a complete response at that time with no serious adverse events. We understand that the patient tolerated the retreatment well through all five days of dosing, which represents a complete cycle of therapy, and although he even reported some physical symptom improvement, he did not achieve an objective response. A week following completion of treatment, the retreated patient experienced some deterioration in physical well-being including fluid in the lungs and elevated liver enzymes. While these fall in line with the SL-401 toxicity profile, our guess is that these are actually not drug-related. On the fluid accumulation in the lungs, while this could be related to capillary leak syndrome, the dose-limiting toxicity with SL-401 at higher doses, we note that capillary leak with SL-401 is most commonly observed at the time of dosing and typically resolves completely between each of the daily doses administered. Thus, the one-week delay to the event leads us to believe that this is not likely drug-related. Furthermore, we believe that pulmonary edema by itself is not a common presentation of capillary leak syndrome. Liver enzyme elevations with SL-401, on the other hand, are associated with a delayed onset relative to dosing (onset is typically between days 5-8 with resolution by days 15-18), but we believe that this is likely not drug-related based on the fact that the patient experienced elevated liver enzymes immediately prior to the start of his retreatment cycle. In addition, we also note that these adverse events were transient with the patient subsequently recovering sufficiently to begin treatment with alternate chemotherapy.

Retreatment Data Supports Strategy To Give Multiple Cycles In Phase 3. Although early and limited to only two patients, we are encouraged by the safety of SL-401 retreatment. 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 already-encouraging single-cycle efficacy without a meaningful increase in capillary leak syndrome or liver enzyme elevations. As a reminder, a single cycle of SL-401 has resulted in an 86% objective response rate in BPDCN and 25% of patients with acute myeloid leukemia experiencing tumor shrinkage. From an efficacy standpoint, we are not too concerned about the lack of an objective response in either of the two retreatment patients. Retreatment in the context of these two patients is suboptimal, as the patients had both been off drug for months (and over a year in the most recent case), had highly progressive disease, and were heavily pretreated. In the upcoming Phase 3 trials in BPDCN and acute myeloid leukemia, investigators will be allowed to dose SL-401 once daily for five days at the start of each three-week cycle, with treatment available to patients until disease progression.

Updated SL-401 Data At ASH This Weekend. STML will have five presentations at the American Society of Hematology (ASH) meeting (12/7-10) in New Orleans, including one on the first retreated patient with BPDCN who had received a second cycle of SL-401 (refer to our STML note from 11/14/13 for more details on the first retreatment patient). Investigators will also present preclinical data of SL-401 in additional indications including multiple myeloma and chronic eosinophilic leukemia (a rare hematologic cancer) as well as an oral presentation regarding preclinical data for SL-101 in FLT3-ITD acute myeloid leukemia.

BUY

Price target \$60.00

Price \$22.77

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Company Description

Stemline Therapeutics, Inc. (STML) is a New York, NY-based clinical-stage biopharmaceutical company, specializing in the development of oncologic drugs that target cancer stem cells (CSCs) and tumor bulk. Cancer stem cells are thought to drive cancer progression, metastasis, and chemotherapy resistance. STML has two candidates in clinical trials, SL-401, humanized IL-3 linked to diphtheria toxin for third-line acute myeloid leukemia (AML) and for blastic plasmacytoid dendritic cell neoplasm (BPDCN). Phase 2b trials are expected to begin for both indications in 2014. The company's other leading candidate is SL-701, a brain cancer vaccine consisting of synthetic peptides targeting IL-13R α 2 and EphA2. Phase 2b are expected to begin in both pediatric glioma and adult second-line glioblastoma multiform (GBM). STML also has a portfolio of preclinical candidates targeting both solid and blood cancers. The company has a proprietary discovery platform targeting CSCs, StemScreen.

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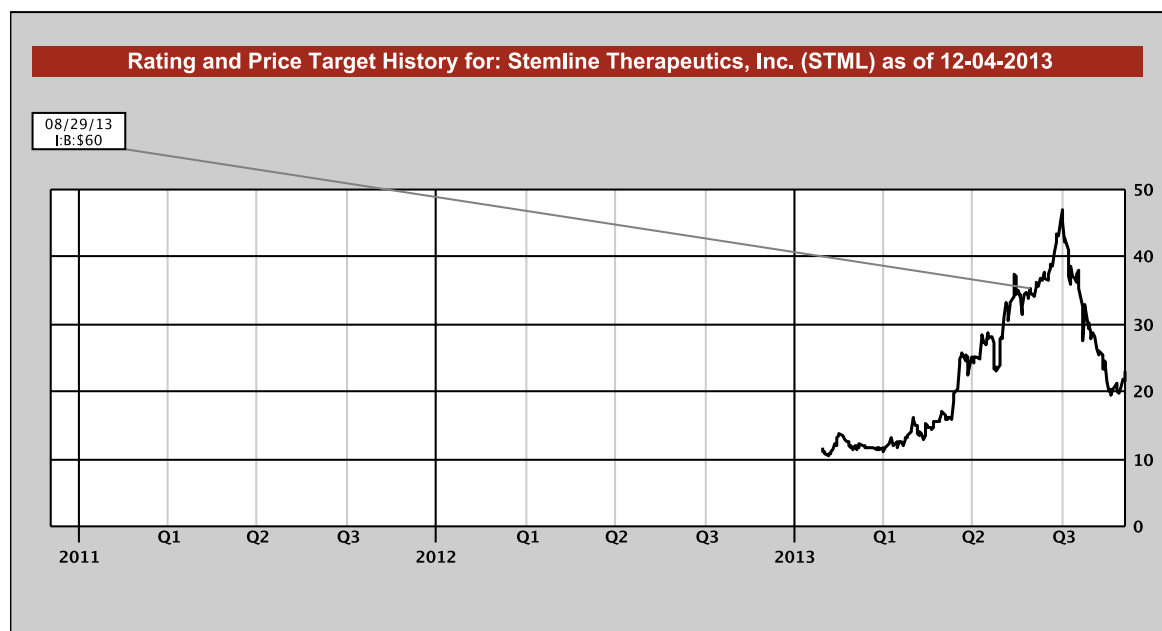
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