FLASH NOTE

Company Update

USA | Healthcare | Biotechnology

November 8, 2013

Jefferies

Stemline Therapeutics (STML)

No New Update In ASH Abstracts – Retreatment Data In December

BUY
Price target $60.00
Price $25.32

EQUITY RESEARCH AMERICAS

Key Takeaway

STML's ASH meeting abstract for the BPDCN Phase 1/2 trial did not disclose any new information on the efficacy of SL-401. There is new mention of transient Grade 3 adverse events not cited in the ASCO 2013 poster, but we do not view these as material changes to our thesis. The next key driver will be data from a second cycle of retreatment for at least 1 patient with BPDCN to be presented at ASH.

ASH Abstracts Notes Grade 3 Toxicities. The ASH abstract for the blastic plasmacytoid dendritic cell neoplasm Phase 2 trial reported that there were 3 Grade 3 toxicities among the 6 patients enrolled as of August 2013. Two patients had Grade 3 liver function test elevations. Both increases resolved to Grade 2 in less than 24 hours. We do not see this as a reason for undue concern, as transient Grade 3 liver enzyme elevations were also observed among the AML patients treated with SL-401, as well as with a related approved lymphoma drug, Ontak. Additionally, one patient had a "brief" episode of Grade 3 neutropenia and thrombocytopenia. All three were deemed to be drug-related, but the transient nature of the side effects leaves us still confident in the safety profile. That said, it is odd that the ASCO 2013 poster presented on the same data set reported that "there were no Grade 3 toxicities."

Critical Data On Second Cycle Of Treatment To Come At ASH In December. As the abstract submission deadline was on August 18, the efficacy data reported in the ASH abstract were identical to the data from our initiation report. Five patients out of six responded to therapy, with four patients experiencing a complete response and one patient experiencing a partial response. The duration of responses were variable and in line with the data from ASCO with the CRs at 11+ (ongoing), 5, 3, and 1 months, and the PR at 1 month. The abstract also noted that additional patients were being accrued to the study. These new data, which we believe will include data on at least one patient retreated with a second cycle of SL-401, will be the focus for investors at ASH, December 7-10 in New Orleans. The pivotal trial in BPDCN is still expected to begin in 1H14. As a reminder, patients in the Phase 1/2 received a single cycle of SL-401. We believe that efficacy should improve with multiple doses, without a dangerous increase in the rate of capillary leak syndrome, which is the dose-limiting toxicity for SL-401.

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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 peptudes targeting IL-13Rα2 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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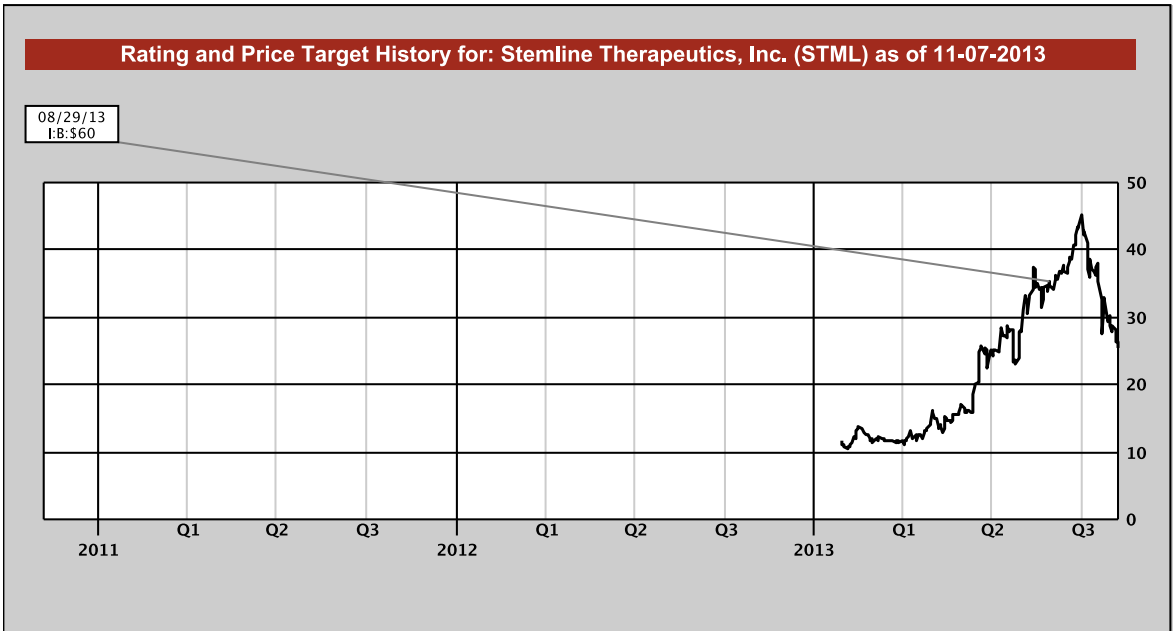

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