

Stemline Therapeutics (STML) Update From Recent Meeting With STML Management

Key Takeaway

During our recent meeting with STML, management highlighted the recent completion of commercial scale product for SL401 and SL701 and provided an update on new indications for SL401. We are encouraged by the feedback on these new indications, which remain upside to our valuation. We continue to value STML entirely on SL401 prospects but see SL701 as a promising early-stage asset.

STML Has Completed Commercial Scale Manufacturing. Management provided an update on its commercial-scale good manufacturing practices (GMP) compliant manufacturing for its products SL-401 and SL-701. The company has completed production of the active pharmaceutical ingredient (API) and is moving into final formulation work and fill and finish. The company plans to file its upcoming INDs with this manufacturing information mid-year as expected.

Pivotal Studies Of SL401 In AML And BPDCN Remain On Track. For the Phase 3 trial in third-line AML, STML notes that they have selected a contract research organization (CRO) and are planning for initiation by 4Q14/1Q15. STML is confident in enrollment of this trial based on the global experience of their CRO and the lack of competitive options in this line of therapy. In BPDCN, a rare lymphoma, the company plans to initiate this pivotal study in 2H14. In the ongoing Phase 2 trial, the company believes that the third patient scheduled for retreatment in mid-December (see note 12/9/13) may not have been retreated. Separately, we have learned that the second retreated patient died in December, shortly after SL401 retreatment, which indicates the advanced nature of his disease and underscores our hesitation in overinterpreting his lack of response to retreatment.

STML Intends To Develop SL401 For New Indications With Institutional Collaborators. STML discussed potential new indications for SL401 including rare IL3-receptor expressing indications such as hairy cell leukemia, mastocytosis, and hypereosinophilic syndrome. We are encouraged by the Mayo Clinic's interest in conducting a single center study in mastocytosis and hypereosinophilic syndrome. Mayo has offered to start by pulling marrow and tissue from banks to do screening for high IL3-expressors. The company is currently considering its clinical strategy in these indications, but they are encouraged that the Mayo Clinic has indicated sufficient patient numbers at their own site to singlehandedly enroll a pilot study. The company has also received interest from MD Anderson, which is another key referral center for these rare disorders. Separately, a group led by Ohio State may enroll a company-sponsored trial in hairy cell leukemia trial. The company also continues to work with Dana Farber on testing SL401 in multiple myeloma patients. Preclinical synergy has been demonstrated with Revlimid, but the next step may involve a pilot study of SL401 with Pomalyst in relapsed/refractory MM, starting with 1-2 cycles of SL-401 as monotherapy prior to adding Pomalyst for subsequent cycles. All of these studies may start in 2H14 once GMP-compliant drug is available. We see these trials as a promising way to potentially expand the application of SL401 among high-need patients.

SL701 Update. STML provided an update of its clinical development plans for SL701 for brain tumors, noting that they had selected a CRO for the adult study and were intending to take the drug into early recurrent disease following radiation and surgery and adjuvant temozolomide but before treatment with Avastin. Co-primary endpoints will include overall survival and response rate at 12 months among 80 patients. The company believes that strong response rates could provide a pathway for accelerated FDA approval. Although we do not currently include SL701 in our valuation, we are encouraged by its early single agent activity.

BUY

Price target \$60.00

Price \$30.22

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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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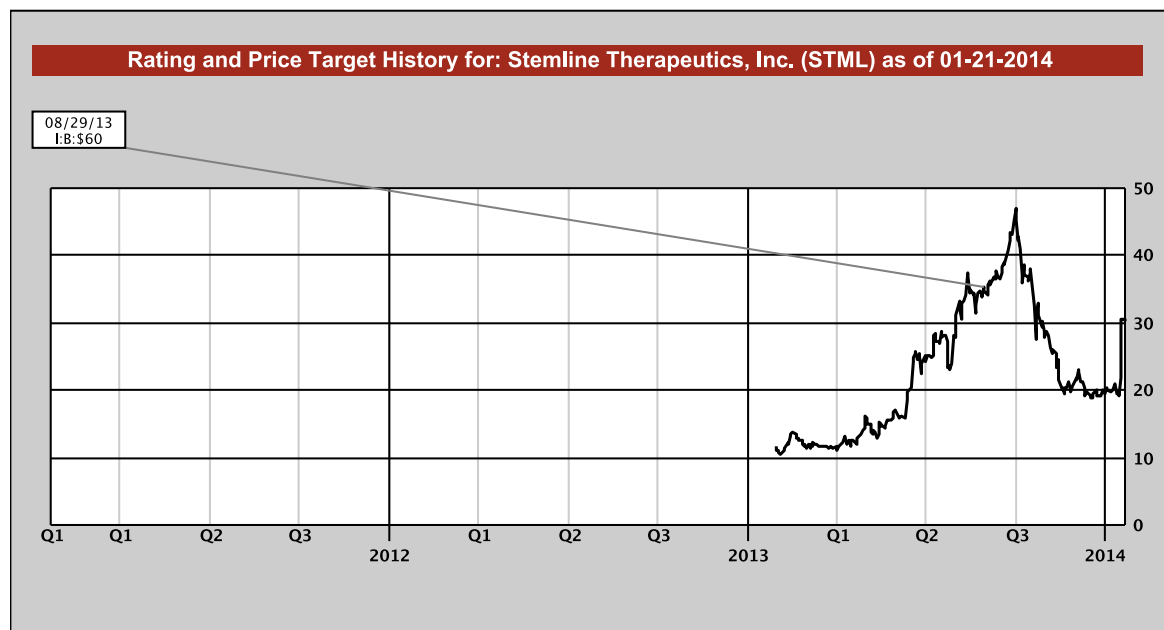
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