FLASH NOTE

Company Update

USA | Healthcare | Biotechnology

October 21, 2013

Jefferies

OncoMed (OMED)

Incremental New Data For Truncated Demcizumab Dosing In Lung Cancer

BUY

Price target $27.00

Price $14.76

EQUITY RESEARCH AMERICAS

Key Takeaway

OMED presented slightly updated Phase 1b data for its DLL4 inhibitor demcizumab in combination with chemotherapy in non-small cell lung cancer (NSCLC). Although these data are supportive of the safety of truncated dosing for demcizumab so far, data are still very early. Further updated on truncated dosing in pancreatic cancer will be presented at the ASCO GI meeting in 1Q13 to validate the safety and efficacy of this strategy.

Background: Phase 1b Trial Was Modified To Include Truncated Dosing Regimen Following Cardio Toxicity Signal. Oncomed's demcizumab is currently in Phase 1b combination therapy trials in patients with non-small cell lung cancer (NSCLC) and pancreatic cancer and a Phase 1b/2 trial in combination with paclitaxel in ovarian cancer. Phase 2 trials are on track to start in 2014. As a reminder, a key concern has been the association between demcizumab and cardiovascular toxicity. Following several interventions to try to lower the rate of heart failure and pulmonary hypertension, the Data Safety Monitoring Board (DSMB) most recently recommended that the protocol be revised to allow only up to 70 days of demcizumab with chemotherapy, followed by chemotherapy alone. In lung cancer, patients would receive up to receive 4 cycles of demcizumab with carboplatin-Alimta followed by completion with carboplatin-Alimta and Alimta maintenance. A key question for OMED is whether the truncated dosing to less than 70 days will be effective on improving responses, and ultimately, overall survival, and whether this approach will avoid CV toxicity.

Incremental AACR Update To Ph1b Trial Includes Some New Patients On Truncated Dosing. At the AACR-NCI-EORTC meeting in Boston, OMED provided an updated set of data from the ongoing Ph1b trial, including early data from 4 patients in the new truncated 7.5mg/kg dose cohort. The key data from this poster include data from a total of 7 patients who have received truncated dosing, three 5mg/kg patients who had already been enrolled when the protocol was amended and the four new patients assigned to 7.5mg/kg. Of these seven patients who were on study for 17-175 days, four had been assessed for objective response, in which there was 1 partial response (PR) and 3 stable diseases (SD). We note that the data from the recently initiated 7.5mg/kg cohort are still not mature, and we expect the response rate to improve as more patients are deemed evaluable. We note early signs of toxicity in the 7.5mg cohort appear to be no worse than those seen in patients dosed at 2.5mg/kg and 5mg/kg, and in fact, are numerically lower than for other dose cohorts. However, an investigator to whom we spoke noted that he expected the low rates of adverse events in the 7.5mg/kg cohort to rise as patients are exposed to longer durations of therapy. Nevertheless, we are encouraged by early signs of tolerability of the higher dose, although efficacy remains unanswered. Efficacy may continue to suffer from interpretabilty of the combination data given the lack of a control arm.

Demcizumab Remains High-Risk, High-Reward. Oncomed noted that it intends to use these data to inform its dosing and design of the Phase 2 trial in NSCLC to start in 2014. We highlight instances where truncated dosing has been effective. For instance, anthracyclines are associated with a cumulative accelerating risk of heart failure, and patients are limited to a certain lifetime exposure limit to the class, but it has become a mainstay of treatment in leukemias, lymphomas, sarcomas, breast and ovarian cancer. On safety, while the data to date would suggest truncated demcizumab dosing should not lead to an increase in CV risk, there still remain relatively few patients treated with a short course of therapy and the cardiovascular safety of even 70 days of demcizumab still needs to be proven. Thus, our valuation already includes a discounted probability of success (10-20%) to reflect this risk.

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Company Description

OncoMed Pharmaceuticals (OMED) is a Redwood City, CA-based biopharmaceutical company that is a leader in the science behind cancer stem cells (CSCs), which are thought to drive cancer progression, metastasis, and chemotherapy resistance. Using proprietary technology, OMED has generated five clinical stage candidates targeting CSC pathways. Four of these compounds are being developed under two pharmaceutical partnerships with GSK and Bayer. The lead wholly owned drug is demcizumab, an anti-DLL4 antibody currently in Phase 1b trials in pancreatic, lung and ovarian cancer. Close behind in development are OMP-59R5, an anti-Notch2/3 antibody, OMP-52M51, an anti-Notch1 antibody, vantictumab, an anti-Fzd7 antibody, and OMP-54F28, a Fzd8-Fc fusion protein.

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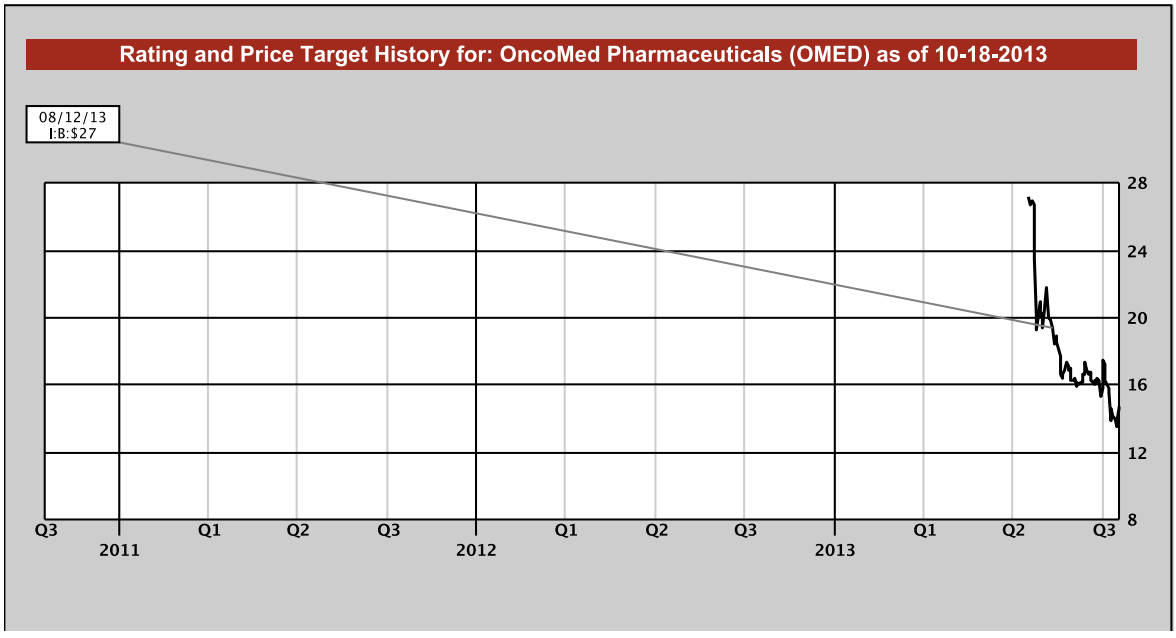
• OncoMed Pharmaceuticals (OMED: $14.76, BUY)



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