

OncoMed (OMED)

Jefferies 2014 Global Healthcare Conference

And ASCO Key Takeaways

Key Takeaway

At ASCO, the 5mg/kg truncated demcizumab dosing arm in its NSCLC study continues to show safety although efficacy is too early to determine. Based on commentary from our conference, we expect the 5mg/kg dose to be taken forward into the Phase 2 trials later this year. Although no dose-limiting toxicity was seen for OMP-54F28 at 20mg/kg, management commentary points to a 10mg/kg dose for Phase 1b trials.

5mg/kg Truncated Demcizumab In Lung Cancer Shows One Partial Response With No CV Events. At ASCO, OMED presented an incremental update to its ongoing Phase 1 trial of demcizumab in combination with pemetrexed and carboplatin in patients with first-line non-squamous NSCLC. Namely, OMED included initial data from seven patients receiving a truncated 63-day 5.0mg/kg demcizumab regimen in addition to the previously described 32 patients receiving between 2.5-7.5mg/kg. As a reminder, truncated dosing was a solution employed by OMED to address concern around a possible association between demcizumab and cardiovascular toxicity. Of the 4 evaluable truncated 5.0mg/kg patients, there was one new partial response and three new stable diseases. The efficacy signal is difficult to compare to chemotherapy alone given the small number of patients in this cohort. Median progression free survival (mPFS) was not yet reached for the truncated 5.0mg/kg cohort. There were no incidences of Grade 3 cardiopulmonary toxicity in the 16 patients receiving truncated dosing and the safety profile was in line with expectations. We await longer followup to determine whether this truncated 5mg/kg dose will be safe from a CV standpoint, as we estimate that patients will need to be on study for at least 150 days to account for time for sufficient drug clearance. OMED expects to begin at least one Phase 2 trial by the end of the year.

10mg/kg OMP-54F28 (FZD8-Fc) Is The Likely Dose For Phase 1b. In the 26 patients who have been dosed in the solid tumor trial, including the highest dose of 20mg/kg every three weeks, no DLTs have been encountered and the MTD was not reached. The drug is expected to have on target bone toxicity, and although there were technically no dose-limiting toxicities (DLTs), there was minor Grade 2 fracture after 6 cycles of therapy in the 20mg/kg arm. Given the fact that this dose is twice the estimated target efficacious dose based on animal models, we expect the three Phase 1b combination trials will use the 10mg/kg going forward in hepatocellular, ovarian, and pancreatic cancer. There have yet to be any responses as monotherapy, although several patients had stable disease.

OMP-59R5 Maximum Tolerated Dose (MTD) Has Not Been Reached. In the PINNACLE Phase 1b/2 study of 59R5 in combination with etoposide and platinum (EP) for untreated small cell lung cancer, there were no dose-limiting toxicities (DLT) seen in the 12.5mg/kg dosing arm and dose escalation has continued to 15mg/kg. To date, only one DLT has been seen (Grade 3 nausea in 10mg/kg arm). On the efficacy side, the data in the poster were consistent with the abstract: 9 of 10 evaluable patients had a partial response, including all four in the 10mg/kg group. Six patients remain on therapy. While encouraging, response rates with chemotherapy alone in SCLC are typically very high. The Phase 2 portion of the trial is still expected to begin later this year.

BUY

Price target \$48.00

Price \$23.03

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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, vantiactumab, an anti-Fzd7 antibody, and OMP-54F28, a Fzd8-Fc fusion protein.

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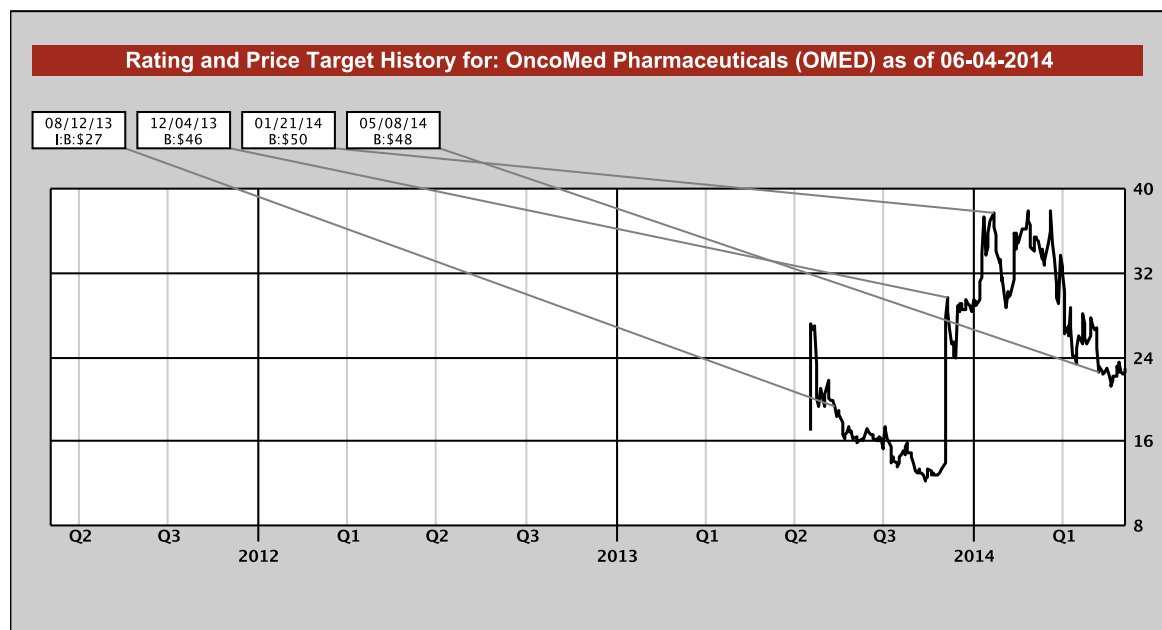
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Other Companies Mentioned in This Report

- OncoMed Pharmaceuticals (OMED: \$23.03, BUY)



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			Count	Percent
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