FLASH NOTE

Company Update

USA | Healthcare | Biotechnology

October 21, 2013

Jefferies

OncoMed (OMED)

Signals Of Activity For Anti-Notch-1 And Fzd8-Fc Program At AACR Meeting

BUY
Price target $27.00
Price $15.12

EQUITY RESEARCH AMERICAS

Key Takeaway

At the AACR-NCI-EORTC meeting, OMED presented first-in-human data for two of its collaborative programs, the anti-Notch-1 and Fzd8-Fc programs, each with some evidence of prolonged stable disease in select solid tumors. Separately, OMED presented promising initial data from the ongoing Phase 1b trial of truncated demcizumab dosing in pancreatic cancer, with further data expected at ASCO GI in 1Q14.

First Clinical Data Presentation Of OMP-52M51 Shows Early Efficacy. OMED presented Phase 1a data for its cancer stem cell (CSC) targeting antibody OMP-52M51 (anti-Notch1) in patients with advanced solid tumors. The presentation included data from the first 11 patients enrolled across the first four dosing cohorts of 0.25, 0.5, 1, and 2.5mg/kg every 4 weeks. Adverse events included mild to moderate diarrhea (63%), nausea (27%), fatigue (18%), and rash (18%). Diarrhea is an expected on-target toxicity of Notch1 inhibition. Management highlighted early efficacy signals, as two of the first 11 patients have had stable disease for >120 days, including a refractory colorectal cancer patient with stable disease for 190 days (in addition to tumor shrinkage) as well as a treatment-refractory HER2- breast cancer patient with stable disease for >140 days. Notably, both colorectal and HER2- breast cancer were tumor types the company had predicted would respond well to therapy, given Notch1 is up-regulated in these tumor types, as well as in pancreatic, esophageal, gastric, small cell lung cancer, and cholangiocarcinoma. Notch1 activation status in these two stable disease patients is currently being assessed. In the expansion cohort of this study, patients with Notch1 activation (determined by a biomarker test) will be selected for treatment with OMP-52M51.

Update On Anti-Wnt Program Shows Promise In Difficult-To-Treat Tumor Types. OMED also updated its anti-Wnt program, including vantictumab (anti-FZD7) and FZD8-Fc. The first-in-human Phase 1 trial for FZD8-Fc is nearly complete with 22 patients dosed between 0.5mg/kg and 15mg/kg q3w. Tolerability was demonstrated across the dose range, with muscle spasms, fatigue and taste changes being the most common AEs. Changes in bone biomarkers have not been seen to the same extent that they were for vantictumab. Per protocol, two patients required zoledronic acid administration, which was able to reverse the elevation in the β-CTX marker. On efficacy, two patients with desmoid tumors, one with renal cell and one with pancreatic (>160 days) tumors all were on study drug longer than 100 days. Three Phase 1b trials on top of chemotherapy will be initiated in late 2013/early 2014. OMED also presented biomarker data for vantictumab, which showed inhibition of the wnt pathway in hair follicles and tumors. The drug has demonstrated single-agent activity in neuroendocrine tumors, and OMED plans to initiate three Phase 1b trials by year-end.

Update From Demcizumab Pancreatic Cancer Phase 1b Supports Truncated Dosing, But Focus Remains On Abraxane Combination Cohorts At ASCO GI In 1Q14. OMED presented data from its ongoing Phase 1b trial of its anti-DLL4 demcizumab in combination with gemcitabine, including encouraging data from three patients receiving truncated dosing, two of whom achieved a partial response (PR) and one stable disease (SD) with no signs of cardiotoxicity. As a reminder, a key concern with demcizumab has been an association with cardiovascular toxicity, and 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. 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. Although we are encouraged by the lack of further signs of cardiac toxicity with truncated demcizumab dosing, we are particularly interested in data from truncated demcizumab in combination with Abraxane and gemcitiabine, which will be presented until the ASCO-GI meeting in January. OMED expects to begin Phase 2 trials in pancreatic cancer in 2014.

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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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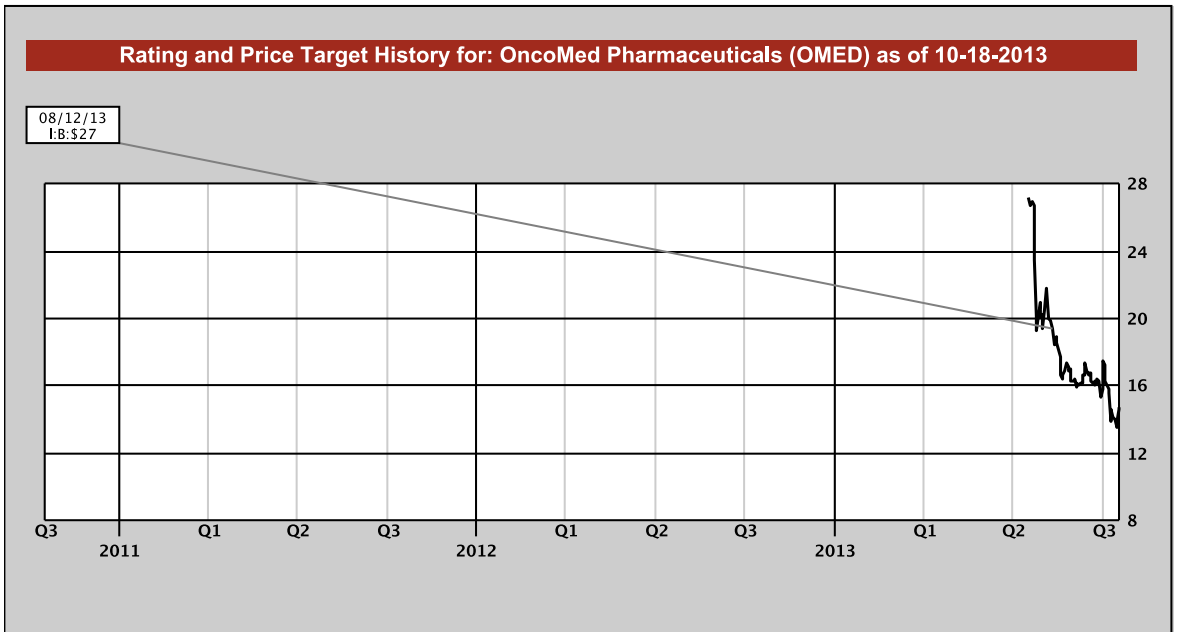

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