FLASH NOTE

Company Update

USA | Healthcare | Biotechnology

January 15, 2014

Jefferies

OncoMed (OMED)

ASCO GI: Notch-2/3 Data Looks Promising - Waiting For Demcizumab Update

BUY
Price target $46.00
Price $34.54

EQUITY RESEARCH AMERICAS

Key Takeaway

In advance of the ASCO GI meeting this weekend, abstracts were posted online, including one abstract each for OMED's anti-Notch2/3 OMP-59R5 and anti-DLL4 demcizumab in pancreatic cancer. OMP-59R5-Abraxane-gemcitabine shows promising rates of objective response, with unexpectedly benign safety. We also expect a first look at demcizumab with gem-Abraxane at Friday's poster session.

OMP-59R5-Gem-Abraxane Shows An Encouraging 40% Response Rate. In the abstract published in advance of the 2014 Gastrointestinal Cancers Symposium (ASCO GI) in San Francisco (1/16-1/18), OMED included early data from its ongoing Phase 1b/2 ALPINE trial of its fully humanized IgG2 anti-Notch2/3 antibody OMP-59R5 in combination with gemcitabine (gem) or gem-Abraxane for untreated metastatic pancreatic cancer (mPC). Specifically, patients were dosed with 2.5-10mg/kg OMP-59R5 in combination with 1,000mg/m2 gem and 125 mg/m2 Abraxane. At the time of the interim analysis, 4 patients in each of the first four cohorts were evaluable by RECIST with 3 patients each in the 2.5 mg/kg+gem and 5 mg/kg+gem cohorts achieving stable disease (SD), 2 patients in the 5mg/kg +gem+Abraxane arm achieving partial response (PR) and 1 achieving SD, and 2 patients in the 10mg/kg+gem+Abraxane achieving PR and 2 achieving SD. The response rate of 40% in the triple combination arms is promising relative to the 23% response rate seen historically with gem-Abraxane, and we believe that there may be some data at ASCO GI on Notch 3 overexpression (which occurs in 70% of pancreatic cancer patients) and its correlation with activity. A strong correlation may create one of the first instances of a biomarker-driven drug in pancreatic cancer and even further enhance an already-promising response rate.

OMP-59R5 Safety Actually Improving When Chemo Is Added. Although single-agent trials of OMP-59R5 have shown grade 3 diarrhea as the main dose-limiting toxicity (DLT) with a maximum tolerated dose (MTD) of 7.5mg/kg every other week, OMP-59R5 is a rare instance where safety actually looks better in combination with chemotherapy. Specifically, the Phase 1b has already dosed to 10mg/kg OMP-59R5 in combination with gem+Abraxane with none of the patients evaluable for safety having experienced a DLT and cases of diarrhea to date all being mild-to-moderate and manageable. This confirms the company's hypothesis that OMP-59R5 diarrhea is a function of cells in the GI tract that are eliminated by chemotherapy. As a result, the company plans to continue dose escalation, with the goal of defining a dose for the start of the randomized Phase 2 portion by mid-2014.

First Demcizumab-Gem-Abraxane Combination Data in Pancreatic Cancer at ASCO GI. Although the data were not updated in the abstract, we remain focused on the updated data from OMED's ongoing Phase 1b trial of its anti-DLL4 demcizumab in combination with gemcitabine and Abraxane in the treatment of pancreatic cancer. As a reminder, at the AACR-NCI-EORTC meeting in October, 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. 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. What will be new at ASCO-GI is a first look at the triple combination of truncated demcizumab with gem-Abraxane.

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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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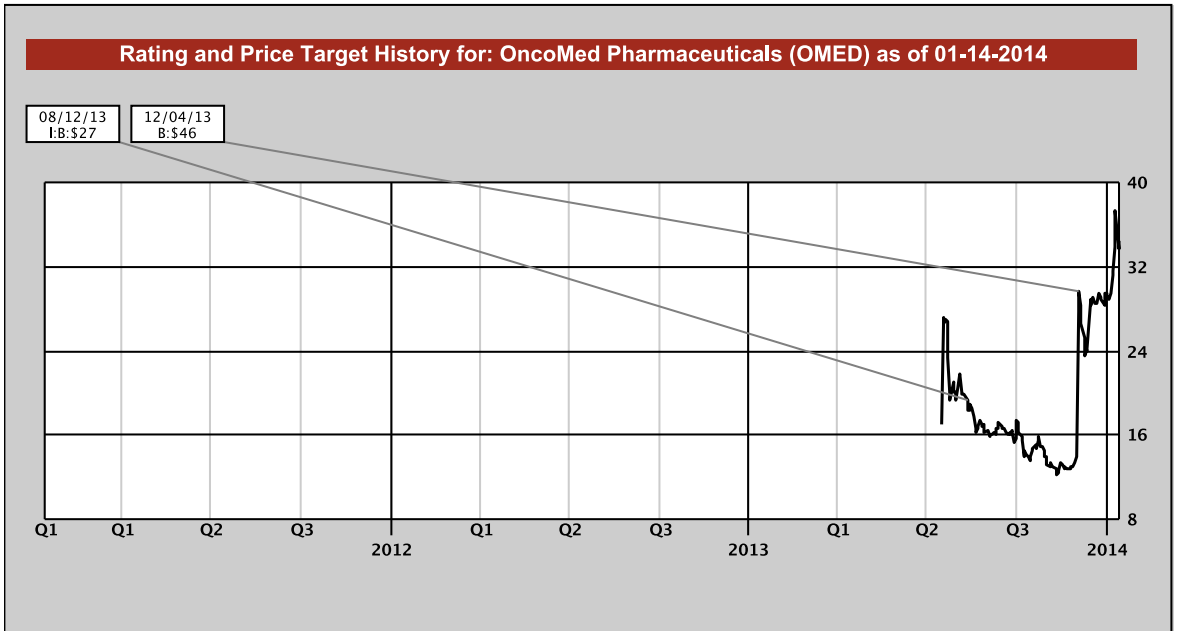

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