FLASH NOTE

Company Update

USA | Healthcare | Biotechnology

June 16, 2014

Jefferies

OncoMed (OMED)

Enrollment Halt On Wnt Programs Due To Bone Toxicity – Expect Limited Delay

BUY
Price target $48.00
Price $22.71

EQUITY RESEARCH AMERICAS

Key Takeaway

OMED voluntarily halted its two Phase 1 clinical Wnt programs that are partnered with Bayer (vantictumab [Fzd7] and OMP-54F28 [Fzd8]). As the Wnt pathway is directly associated with bone growth and signs of bone turnover were already seen in both trials, the halt does not come as a complete surprise. OMED believes the amended trial protocol will result in a minimal delay and that new lower dosing will still be in the therapeutic range.

Bone Toxicity Is Part Of Mechanism Of Action. The Wnt signaling pathway is associated with bone growth and research in this pathway has already led to the development of the anti-sclerostin antibodies for the treatment of osteoporosis. The Phase 1 protocol had taken this into account and included measures to monitor bone turnover every 28 days (through β-CTX and DEXA scans) and prophylactic Vitamin D and calcium. If β-CTX doubled or the DEXA scan T-score declined to <-2.5, zoledronic acid would be administered. The exclusion criteria also screened out patients with higher potential for bone loss. OMED believes that the driver for bone loss could be Cmin rather than Cmax or the area under the curve. Thus, more intermittent dosing that allows for the drugs to be washed out may lower the risk for bone toxicity.

The Street Has Already Known About Bone Loss In the Ongoing Trials. From the most recent ASCO update for Fzd8, 6 of 26 patients had experienced doubling of β-CTX and one patient in the highest 20mg/kg every three week dosing arm had a minor Grade 2 fracture. From Friday's press release, another patient also had a minor fracture, making it 2 of 41 patients. For vantictumab, the last update on safety was from Sept 2013, with 1 of 29 patients suffering a fracture. Today's release notes that 8 of 63 patients had minor fractures. Overall, fractures were dependent on duration of therapy and dose level. OMED notes that the fracture rates for tamoxifen and aromatase inhibitors are around 10%.

Trial Protocols Likely Amended For More Prophylaxis, And Less Frequent, Higher Dosing. We expect the biggest change to the amended trial protocols to be the inclusion of prophylactic zoledronic acid where it is currently indicated, and stricter exclusion criteria for those more likely for bone loss. The Phase 1b dose for vantictumab ranged from 2.5mg/kg to 7.5mg/kg at q2w and q3w. These doses will be cut substantially and OMED would look to q4w dosing to help ameliorate bone toxicity. Further, OMED would expect to monitor bone levels every 12 days instead of 28 days. Overall, assuming the FDA and study sites agree with the amended protocol, OMED does not expect a significant delay to either program. They could still see data from Phase 1b trials by the beginning of 2015. Importantly, OMED believes that all doses tested going forward will continue to be in the therapeutic range, although this will require confirmation. There have been some signals of single agent activity with the two Wnt programs, although these have mostly been prolonged stable diseases in less common tumors. We believe stronger activity (as well as a better safety window) has been observed with the company's Notch targeting antibodies partnered with Glaxo (GSK LN, Hold, 1,605p).

Financial Impact Limited. Both Wnt programs are licensed to Bayer. OMED is only financing the Phase 1b portions of these two programs before Bayer makes a go/no-go decision. Thus, the delay would have a marginal impact on cash flows for the company. Additionally, Bayer and OMED have additional preclinical collaborations in the Wnt pathway, including oral candidates.

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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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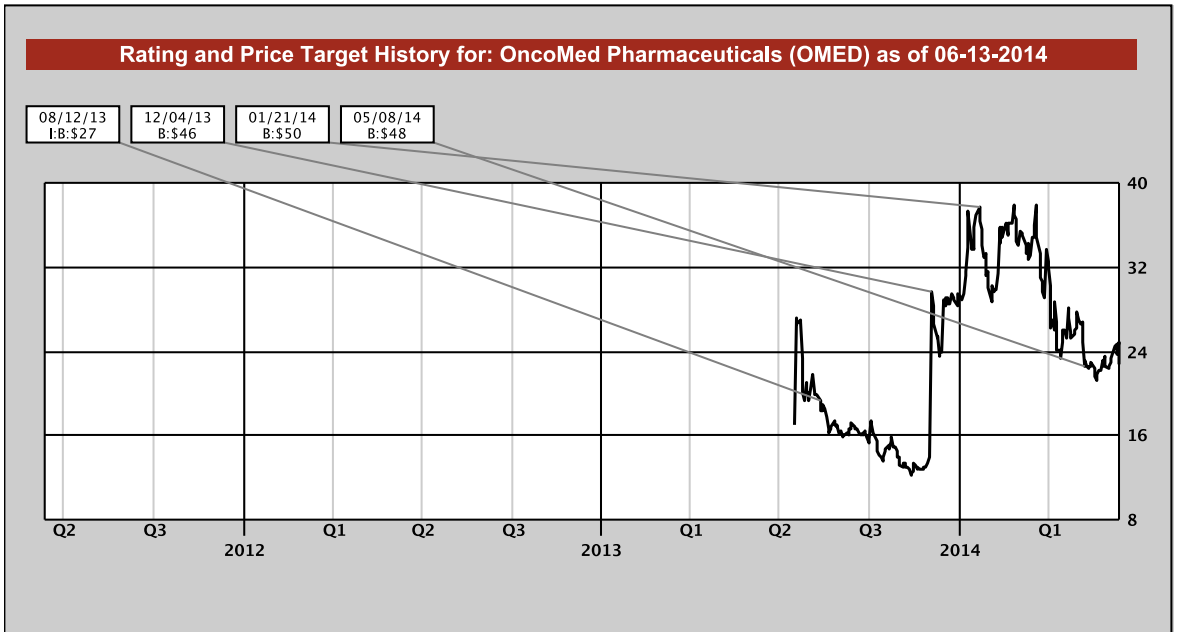
Other Companies Mentioned in This Report

- Bayer AG (BAYN GR: €103.46, BUY)
- GlaxoSmithKline Plc (GSK LN: p1,605.00, HOLD)



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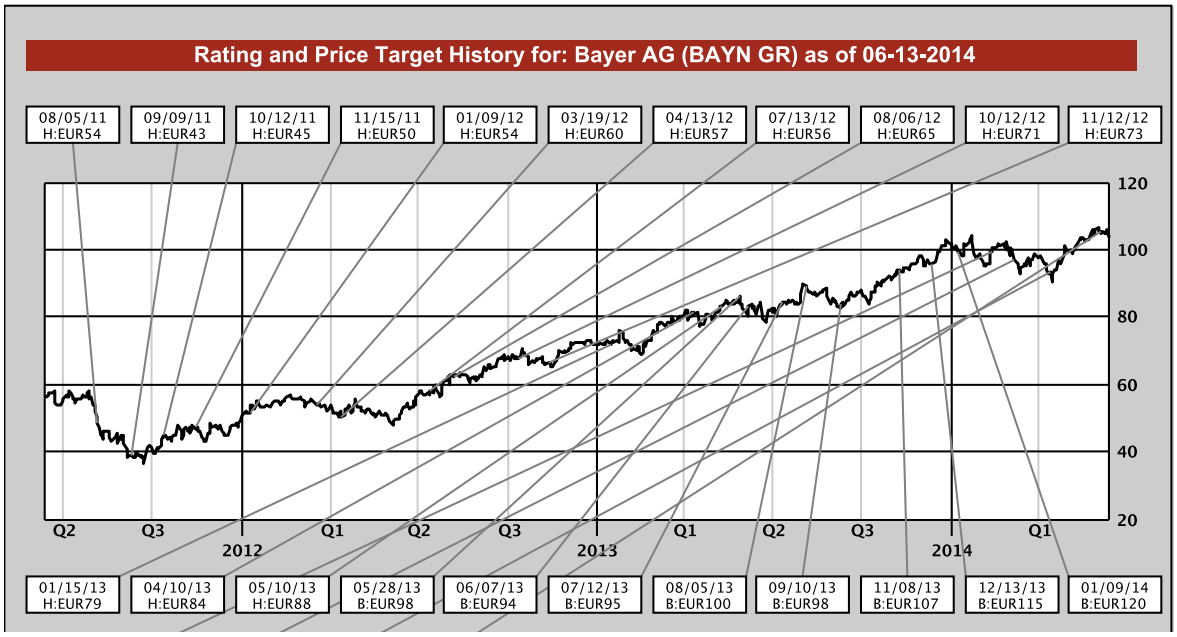

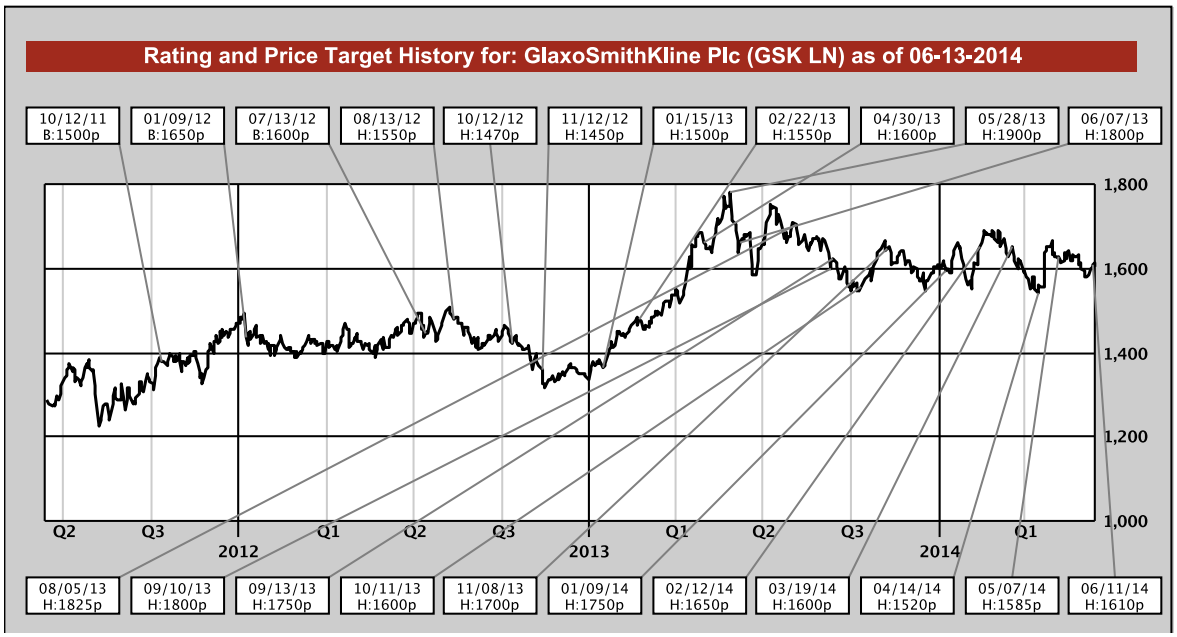

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