FLASH NOTE

Company Update

USA | Healthcare | Biotechnology

September 12, 2016

Jefferies

Celgene Corp. (CELG)

A Bit More Optimism On '0301's Profile Comes Through At Company Presentation

BUY
Bloomberg NASDAQ: CELG
Price target $137.00
Price $104.47^

^Prior trading day's closing price unless otherwise noted.

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Key Takeaway

At a presentation this PM, CELG discussed '0301. Our impression is that the co is more optimistic about what they are seeing from '0301's profile than was conveyed in the PR. While lack of placebo arm, an early data cut, and limited historical data cloud interpretation, we got the sense CELG believes '0301 is having true activity and even if ultimately with a different efficacy profile vs. other agents, could have a unique position as a well-tolerated oral.

Company seemed very optimistic around the endoscopy results: CELG noted they are "very very encouraged" and "pleased" by the data emerging from the endoscopy study. They reiterated that the population tested in the study was particularly challenging, and that in such a group at the relatively early timepoint of 12 weeks, they would expect very few pts to have spontaneous endoscopy improvements-- potentially setting them up to show statistically significant separation from placebo on mucosal healing in a large, controlled ph.III. While a portion of pts achieving 25% reductions was less than we had hoped to definitively confirm true drug activity based on our prior KOL discussions, if baseline SES-CD scores they show are ultimately very high (sicker population), it could make it more likely that even with the more modest improvements indicated by the top-line data that the drug's effects are real and possibly meaningful. The company also reiterated that the timepoint explored, 12 weeks, is very early, and that signals that mucosal healing is beginning to take place are all that should be expected, though the lack of placebo arm or comparable historical data makes this difficult to confirm. They confirmed that they remain comfortable on the size and structure of the ph.III program, and said KOLs indicated to them the full data, when presented, should help increase enthusiasm for enrollment.

Clear enthusiasm around CDAI remissions and possible signals of dose dependence may support potential activity: CELG characterized the CDAI remissions and responses as "outstanding" for this population, and felt they supported the prior data in easy-to-treat pts as well as the ph.III design. We would look for the full data to help contextualize these, and believe CELG may be setting the Street up for less robust symptomatic improvements - certainly than were seen in the prior easy-to-treat study and possibly than have been seen with biologics in less pretreated pts - that still are meaningful in this more pretreated, higher-baseline CDAI population. Interestingly, the company revealed that "a majority" of the many endpoints they explored showed some tendency towards dose response, following a pattern one would expect -- which if clearly confirmed in the detailed data would be a meaningful step towards validating that the drug's efficacy is real, in our opinion. We would still be interested in additional validating details, including predictors of response (e.g., right-sided disease) and correlation between mucosal and symptomatic improvements, when full data are presented.

Positioning as an 'Otezla for Crohn's'? We await full data before drawing more definitive conclusions. Still, we got the sense that that the company's characterization of '0301 as having a "different type of benefit/risk" as an oral, locally-delivered therapy with minimal side effects was suggesting they may view it as being like an Otezla for IBD, in which efficacy across symptomatic and/or endoscopic measures may or may not compare precisely with available/late-stage biologics but that its activity and cleaner side effect profile could give it an important place in the future treatment paradigm.

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Company Description

Celgene Corp. is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of therapies for the treatment of cancer and inflammatory diseases, with mechanisms including immunomodulation and epigenetics. Marketed products include Revlimid, Pomalyst/Imnovid, Abraxane, and Otezla. The company is headquartered in Summit, NJ.

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(Article 3(1)e and Article 7 of MAR)

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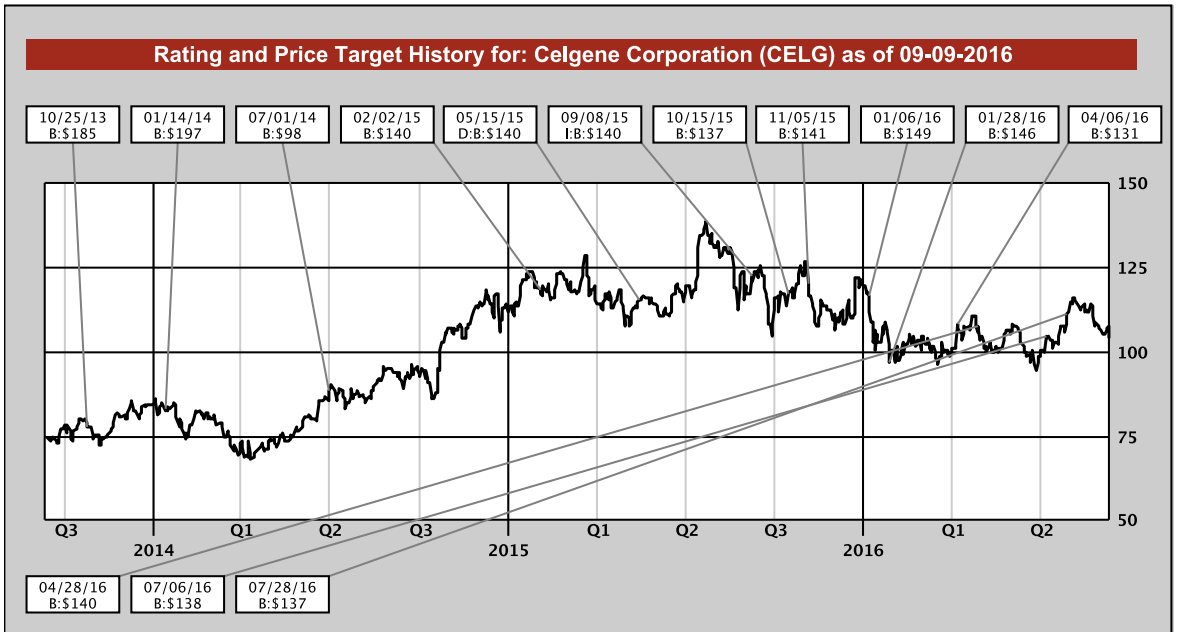
- Celgene Corporation (CELG: $104.47, BUY)



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