22nd November 2016

Healthcare

AstraZeneca

Price 4,326p

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74
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13
15
3%
9%
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2%
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FDA lifts partial hold on H&N trials with durvalumab

Fair Value 5100p (+18%)

BUY

ANALYSIS

- AstraZeneca has announced today that the FDA has lifted the partial clinical hold put on patient
 recruitment in head and neck squamous cell carcinoma (H&N) trials involving durvalumab in
 monotherapy or in combination with tremelimumab. Late last month, EAGLE and KESTREL phase
 III trials saw patient recruitment suspended after the report by AstraZeneca to the FDA of a higherthan-expected incidence of bleeding events. Although patients with H&N cancer are more likely to
 have bleeds, this may have been drug-related, hence the decision to stop including new patients.
- After careful consideration, the agency has lifted the partial clinical hold, suggesting that no
 correlation between extra bleedings and the drug can be established. As a consequence,
 AstraZeneca mentioned that it has already re-opened KESTREL to recruitment whereas EAGLE will
 soon be re-opened too.
- This is good news for AstraZeneca's PD-L1 franchise because head & neck was the second most
 important indication for durvalumab-based treatments after lung cancer and a setback would have
 caused a meaningful sales cut (probably by about one-fifth).

VALUATION

Considering the weight of oncology in AstraZeneca's future sales, as well as its influence on the
profit margin and profit growth, everything has to work well to support an investment case that is
heavily dependent on the pipeline.

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