

## UCB

Price EUR76.85

## Briviact approved in the US while FRAME releases top-line results

Fair Value EUR78 vs. EUR75 (+1%)

NEUTRAL

Bloomberg	UCB BB
Reuters	UCBBt.BR
12-month High / Low (EUR)	85.6 / 61.5
Market Cap (EURm)	14,948
Ev (BG Estimates) (EURm)	14,698
Avg. 6m daily volume (000)	293.2
3y EPS CAGR	30.0%

UCB has received FDA approval for brivaracetam (as Briviact) as an adjunctive therapy to treat epileptic patients with partial-onset seizures (+1 EUR to our FV) and today released top-line results from the phase III trial FRAME. Co-primary endpoints were met although key secondary ones (non-vertebral fracture reduction) were not, while safety requires further investigation. Overall this is positive (+EUR2 to our FV) but detailed results and a second trial are needed to fully assess the value of the drug in this challenging indication of post-menopausal osteoporosis.

## ANALYSIS

- Following European approval for brivaracetam (brand name BRIVIACT) in late January, the FDA has approved the anti-epileptic drug for use in patients suffering from epilepsy with partial onset seizures. The drug should be made available in the US in late Q2 2016, following a 90-day review process by the DEA. As a reminder, brivaracetam features a high safety profile and should be indicated for epileptic patients not responding to one or two other AED. We have modelled EUR476m in peak sales for the drug (of which 60% should be recorded in the US).
- UCB is delivering on its strategy to address all treatment lines in epilepsy with Vimpat as a 1st AE and now brivaracetam in uncontrolled patients. Note that within the company's pipeline, UCB0942, which should readout in Q3 2016, should broaden the company's offering as a last-line AE drug in highly refractory patients (non responders to 4/5 AED with multiples seizures per week).
- Separately, UCB and Amgen announced this morning that romosozumab's (partnership with Amgen) phase III FRAME trial met all its primary endpoints. Results from the STRUCTRE trial (open label) released in early September 2015 gave a positive tone, hence we believe that positive results were anticipated and should not be a major surprise. FRAME is one of the two large multicentric phase III studies ongoing in more than 10,000 postmenopausal women that will be the basis for a filing of the drug in key markets including the US. FRAME is placebo-controlled over the first 12 months and then compares to denosumab for the following 12 months. The primary endpoint was a composite one measuring clinical fracture risk reduction at 12 and 24 months. We said previously that a positive read-out would add EUR5 to our fair value (PoS up to 80% from 60%). Because the secondary endpoint of reduction non-vertebral fractures at months 12 and 24 is not met, we would make half the road (PoS of 70%), waiting for more data to assess the results in details and also because cases of osteonecrosis of the jaw have been noticed. To get a more balanced view about efficacy and safety, we think it is fair to wait for the results to be published in a medical congress and for the second trial to be released too.

## VALUATION

- The news was anticipated following late January's EU approval of brivaracetam. Raising our PoS of success from 90% to 100% adds EUR1 to our Fair Value.
- As far as romosozumab is concerned, we are comfortable with an increase in the PoS from 60% to 70% but we think it is fair to wait for more detailed results from the trial as well as the second one, for a comparative efficacy profile and to get extra safety data before making a definitive assessment. As such, impact on the FV is limited to EUR2 per share.
- We reiterate our Neutral rating.

## NEXT CATALYSTS

- 26th February: FY2015 results

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## Distribution of stock ratings

BUY ratings 63.4%

NEUTRAL ratings 28.4%

SELL ratings 8.2%

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