FLASH NOTE

Company Update

Belgium | Healthcare | Biotechnology

18 October 2018

Jefferies

UCB (UCB BB)

Roza Efficacious in MG but Risk-Benefit May Fall Short of Key Competitor

HOLD
Bloomberg BRU: UCB BB
Price target €73.00
Price €75.94^

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

EQUITY RESEARCH EUROPE

Key Takeaway

Anti-FcRn rozanolixizumab (roza) signs of efficacy in the Phase II myasthenia gravis (MG) study appear below the key competitor, in our view. Furthermore, headache incidence is 57% with three patients (14%) withdrawn on severity. UCB plans to start a further study 2H19E, putting roza c.1 year behind competition in MG. Roza may offer a more convenient subcut admin but based on these data we see concerns of inferior risk-benefit vs. peers. Roza has €5/ share NPV.

Progressing to Phase III on mixed Phase II data: Whilst roza missed the primary endpoint in the Phase II myasthenia gravis (MG) study, UCB is initiating a confirmatory trial 2H19E, on the basis of clinically meaningful improvements across several disease-specific endpoints. This will put roza c.1 year behind competition, with Argenx's efgartigimod Phase III MG trial having started in September. Furthermore, the efficacy profile of roza appears milder based on reported responder rates. Whilst the usual cross trial comparison caveats apply, we note the following response rates (defined as a reduction of 3 or more points from baseline):

- QMG: Roza 38.1% vs. 22.7% placebo; efgartigimod 58% vs. 27% placebo
- MG-ADL: Roza 47.6% vs. 13.6% placebo; efgartigimod 75% vs. 33% placebo

Phase II missed primary endpoint: The Phase II trial evaluated roza vs. placebo in 43 MG patients across two dosing periods. In part one, patients received three once-weekly (QW) infusions of placebo or roza 7mg/kg over a four week period. At the end of this period, treatment with roza led to a non-significant -0.7 change in the baseline-corrected Quantitative MG (QMG) score (p=0.221), therefore missing the primary endpoint. Secondary endpoints were mixed, with a non-significant -1.8 improvement in MG Composite (MGC) score (p=0.089) and a significant 1.4 improvement in MG Activities of Daily Living (MG-ADL) score (p=0.036). Encouragingly, post-hoc analysis suggested a statistically significant absolute change from baseline in the MG-ADL score of -2.0 (p=0.008), which is an established registrational endpoint. In part 2, patients were re-randomised to receive a further three doses of either roza 7mg/kg or 4mg/kg QW, with UCB reporting additional clinically meaningful reductions across all scores. Following two weeks of roza treatment, serum IgG concentrations reduced by 56%, whilst patients who received roza 7mg/kg in both dosing periods had a mean 68% reduction from baseline in total IgG and anti-acetylcholine receptor (anti-AChR) antibodies decreased during dosing period two.

Headache incidence is noteworthy: UCB reports that roza was safe and well-tolerated, in-line with the Phase I programme and PoC ITP study. However, whilst a disparity in headache frequency between roza (57.1%) and placebo (13.6%) arms was expected, we note that the 57% frequency is higher than the 40% rate reported in the Phase IIa ITP trial, and the 33% reported for efgartigimod in its MG trial. Further, three (14%) roza-treated patients were withdrawn from the study, per-protocol, which we assume relates to severe headache, which had not previously been reported with subcutaneous (SC) roza. Recall, severe headache and back pain reported with IV roza led UCB to prioritise the SC formulation. All headaches were considered manageable and resolved with standard treatment. We note that there were no apparent differences in the incidence of infections.

See biggest potential for roza in CIDP: UCB is also targeting a number of other indications including chronic inflammatory demyelinating polyneuropathy (CIDP), where a Phase II study is expected to start 1Q19E. We remain more bullish on roza's potential in CIDP than in MG and ITP and assume $1.5bn peak sales at 30% probability, with $750m in CIDP. Argenx recently announced plans to start an efgartigimod Phase II trial in CIDP in 1H19E.

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Company Description

UCB

UCB is a global biopharmaceutical company established with the acquisitions of Celltech in 2004 and Schwarz Pharma in 2006. The company focuses on the two core therapeutic areas of CNS and immunology, using both small molecules and biologics. UCB's blockbuster epilepsy drug Keppra peaked in 2008 when the US patent expired. The company's key products are Vimpat (epilepsy), Cimzia (rheumatoid arthritis, Crohn's disease and other autoimmune disorders), and Neupro (Parkinson's disease).

Company Valuation/Risks

UCB

Our Price Target is based on an NPV sum-of-the-parts valuation. Risks include: (1) increased competition and/or reimbursement/pricing pressures for the core products; (2) accelerated impact on Cimzia from biosimilars; (3) pipeline setbacks notably Evenity, bimekizumab and rozanolixizumab.

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

Recommendation Published	October 18, 2018 , 02:56 ET.
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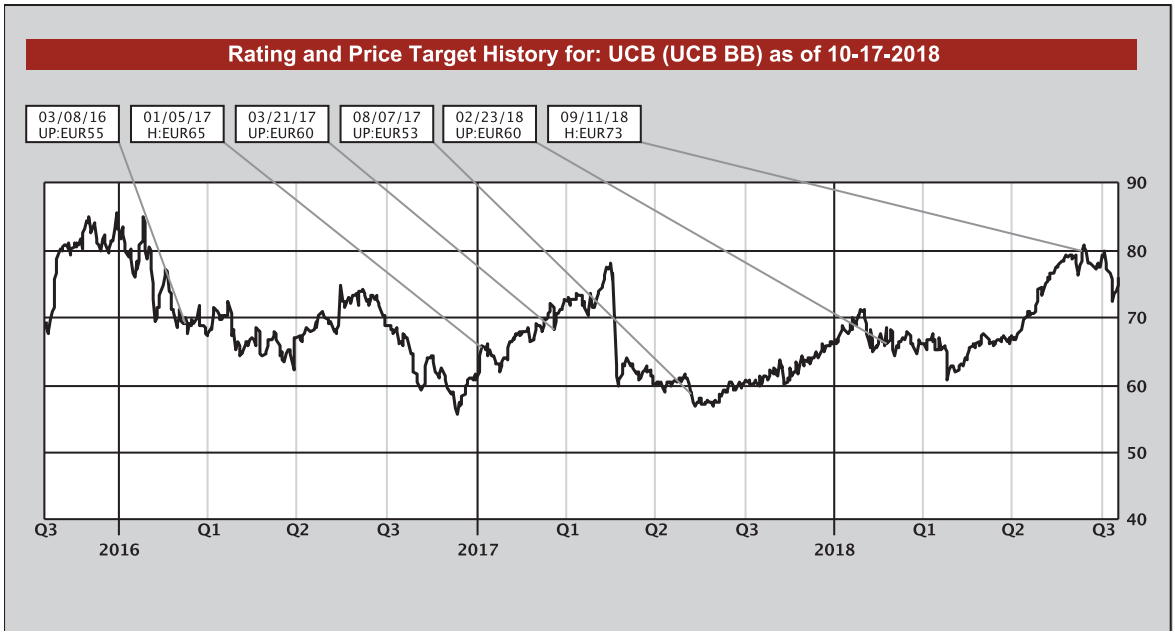

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