

Ablynx (ABLYX BB)

Detailed Capla Phase III Data at ASH Clearly Show Economic & Clinical Benefits

Key Takeaway

Detailed Phase III HERCULES data at ASH underpin our belief caplacizumab for rare blood disorder aTTP is a potential game-changer for Ablynx. Insights into the duration of plasma exchange and hospitalisations clearly show the drug provides a substantial benefit for payers, in our view. We still believe capla's value seems to remain underappreciated. ALX-0171 for RSV and numerous partnered assets could also drive upside. Reiterate Buy.

HERCULES details confirm highly relevant pharmacoeconomic benefits: As previously disclosed, caplacizumab met the primary endpoint and two key secondary measures in the Phase III HERCULES study for acquired thrombotic thrombocytopenic purpura (aTTP), demonstrating a highly relevant clinical benefit, in our view. Importantly the presentation at ASH demonstrated substantial reductions in the duration of plasma exchange (PEX), hospitalisation and ICU, suggesting meaningful benefits for payers. Incremental insights from ASH included:

- Mean days of plasma exchange 9.4 vs. 5.8 (-38%) for placebo vs. caplacizumab, respectively, with volume of plasma 35.9L vs. 21.3L (-41%). Mean days in intensive care 9.7 vs. 3.4 (-65%) and days in hospital 14.4 vs. 9.9 (-31%).
- Using the more recent international TTP working group consensus definition of refractory aTTP there were five episodes on placebo vs. none on caplacizumab ($p=0.018$), in contrast to 3 vs. 0 ($p=0.057$) using the pre-specified definition.
- Organ damage biomarkers normalised more swiftly on caplacizumab.
- Greater granularity on bleeding-related adverse events as 23% vs. 46% so c.2x more common on caplacizumab. Most were epistaxis (nose bleeds) or gingival (gum) bleeds, which were generally mild and resolved without intervention.
- It was noted across both this trial and the Phase II TITAN study, there has not been a death on caplacizumab, perhaps suggesting a mortality benefit.

Our clinician discussions unanimously suggested caplacizumab is likely to become a front line standard-of-care for aTTP. The only caveat raised at the ASH meeting was for patients already on anticoagulants given the bleeding risk.

Potential game-changer for Ablynx: Caplacizumab significantly curtails costly plasma exchange, a risky procedure, reduces the risk of exacerbations, and protects organ damage, providing a window for physicians to resolve the underlying disease. We expect EU conditional approval during 1H18E, with filing to FDA anticipated shortly for 1H19E US launch. Commercialising capla itself we envisage highly profitable \$500m WW peak sales from 70% penetration, assuming it is widely adopted as a standard-of-care, for a €21/share NPV at 90% probability.

ASH debate session noted incremental capla opportunity: The session emphasised the importance of monitoring patients regularly after an episode of aTTP if their ADAMTS13 activity remains deficient. It was almost unanimously agreed that maintenance rituximab use is advisable for refractory aTTP patients with a severe ADAMTS13 deficiency (<10%). Possible use of caplacizumab in this subgroup was also noted, with our clinician discussions suggesting maintenance treatment could be considered for these refractory patients given the benefit despite the risk of mild-moderate bleeds.

Funded to crystallise value: Our forecasts suggest €281m cash at end-Sep, plus \$230m gross proceeds from the recent US IPO, should be sufficient to reach 2020E breakeven assuming capla success.

BUY

Bloomberg BRU: ABLX BB
Price target €29.00
Price €20.39[^]

BUY

Bloomberg OTC: ABLX
ADR Price target \$34.00
ADR Price \$23.93[^]

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

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Company Description

Ablynx is a Belgian biotech company engaged in the discovery and development of Nanobodies, a novel class of therapeutic proteins based on single-domain antibody fragments. The company has alliances with Merck Serono, Merck, Boehringer Ingelheim and Novartis to use its platform technology to generate Nanobodies against specific disease targets. Lead pipeline product caplacizumab (anti-vWF) treats the rare blood disorder thrombotic thrombocytopenic purpura (TTP). Ablynx has partnered ALX-0061 (anti-IL-6R) with AbbVie for rheumatoid arthritis and systemic lupus erythematosus, and has ALX-0171 (anti-RSV) in early-stage clinical development for respiratory syncytial virus infections.

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

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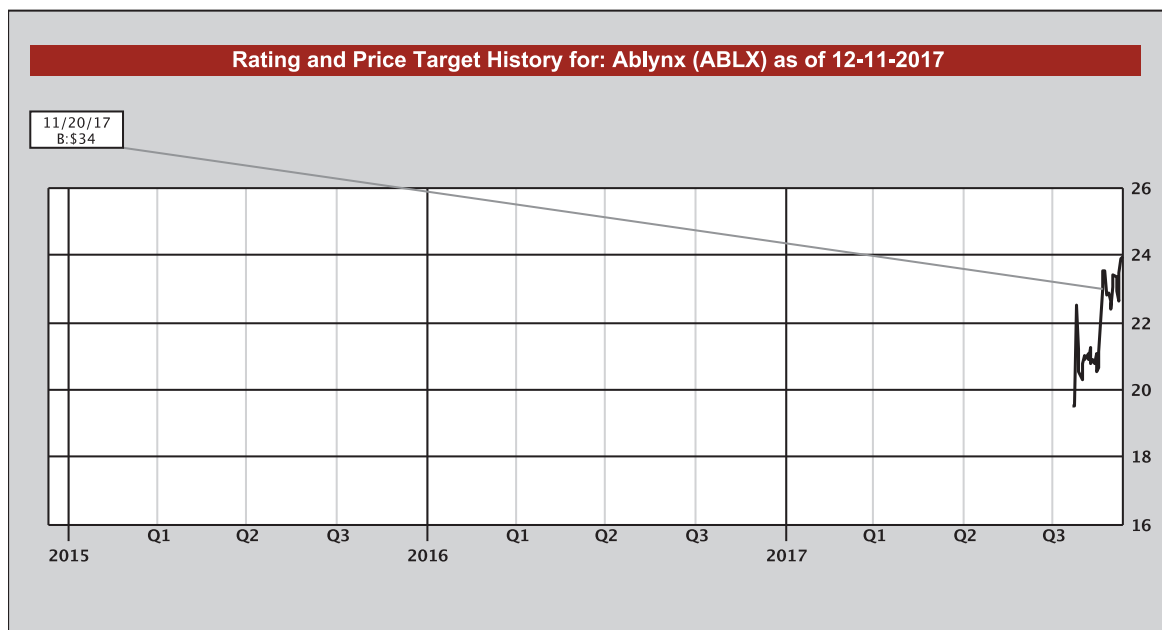
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