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Equity Research Alert

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Antisense Therapeutics Limited (ANP)

Positive PIP opinion

Announcement highlights

Antisense have announced positive feedback on their Paediatric Investigational Plan (PIP) submission from the European regulator with regards to their Phase IIb trial of ATL1102 in Duchenne Muscular Dystrophy (DMD). Antisense also announced appointment of a CRO to manage this upcoming trial. This news moves Antisense one step closer to initiation of their Phase IIb trial and subsequent potential market access.

Wilsons' view

Initial analysis

PIP acceptance looks favourable; to be confirmed at October meeting. Antisense have received positive feedback from the Paediatric Committee (PDCO) of the EMA with regards to Antisense's proposed EU Phase IIb trial design/plan for ATLL102. Our assessment is that there are no substantive reasons as to why the PDCO would not adopt the favourable draft opinion they have released and support an EMA approval for the study. We will receive confirmation on their final decision after the next PDCO meeting to be held on October 15th, at which time we will receive confirmation on final trial design.

European Phase IIb refresher. As a reminder, we anticipate a blinded, parallel arm trial (3 arms, n=108 patients total) evaluating ATL1102 at two doses (25mg and a higher dose tbc) versus placebo. Non-ambulant DMD boys will be treated for 12 months and evaluated for changes in PUL2.0 score as the primary approvable study endpoint. We assess this study will provide adequate clinical data to support a European BLA submission for potential EU marketing authorisation. These details are yet to be confirmed.

Evidence of trial preparations progressing. We note the appointment of Paraxel, a leading global CRO, by Antisense to conduct their EU Phase IIb trial. Trial site scoping and preparations are confirmed to be commenced at > 30 sites. This is critical work to ensure ANP are ready to proceed with the trial once final approvals are received. As a reminder, in Europe, EMA approval allows a company to submit individual trial applications for each relevant EU member state jurisdiction that must then be approved by said jurisdiction to allow for study commencement. We expect a staggered trial start in this respect with some National Competent Authorities progressing faster on trial approvals than others, allowing some jurisdictions to start study recruitment before others. Provided no delays we see an avenue for initial patient recruitment in CY21, if not early 1Q'22.

Earnings implications

None.

Investment view

We maintain our OVERWEIGHT recommendation and risked $0.63 per share price target.

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