WILSONS

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Theme Alert

Sector Healthcare

Company

Antisense Therapeutics (ANP)

The first DMD gene therapy approved

Recommendation OVERWEIGHT

12-mth target price (AUD) $0.36

Dr Melissa Benson
melissa.benson@wilsonsadvisory.com.au
Tel. +61 2 8247 6639

Dr Shane Storey
shane.storey@wilsonsadvisory.com.au
Tel. +61 7 3212 1351

Madeleine Williams
madeleine.williams@wilsonsadvisory.com.au
Tel. +61 3 9640 3834

Announcement Highlights

Sarepta Therapeutics (NASDAQ: SRPT) have announced FDA approval of their gene therapy, ELEVIDYS, for Duchenne Muscular Dystrophy (DMD). This represents the first gene therapy approval in this indication. This advances the profile of new DMD therapies, however its approval still does not solve for the ~50% of DMD patients that have progressed to non-ambulatory stage disease, with the ELEVIDYS FDA label restricted to ambulatory patients aged 4-5 years only (a very small subset of the entire DMD population with unmet need). Sarepta's ELEVIDYS was granted accelerated approval and hence FDA have required commitment from Sarepta to a confirmatory Phase III trial (EMBARK) to support full approval (which is already underway with top line results later this year). If this data is supportive it is expected Sarepta will file for an expanded label to include a broader scope of patient ages, however the EMBARK trial is restricted to ambulatory patients only, thus leaving non-ambulatory still unaddressed by this new therapy.

Wilsons' View

Initial analysis

Continues to be a deficit of options for non-ambulatory DMD patients. There are potentially 3 new DMD drug approvals anticipated (including ELEVIDYS) within the next ~18 months – however none of them address non-ambulatory patients. Alongside ELEVIDYS, another near-term DMD hopeful with an FDA decision (PDUFA) date of 26 Oct 2023 is Santhera Therapeutics' VAMOROLONE – a novel steroid for the treatment of DMD symptoms. This program is also focused on ambulatory patients only. Another is Italfarmaco's GIVINOSTAT which read out positive Phase III results mid last year and is seeking to file for regulatory approvals in major markets – again with a Phase III trial that restricted recruitment to ambulatory patients.

ATL1102 complementary to gene therapies. We view any use of ELEVIDYS, or other future approved gene therapies, as highly complementary to what Antisense's ATL1102 is seeking to achieve in DMD patients. Supportive treatment with anti-inflammatory agents that can potentially slow muscle wastage into fat (i.e. ATL1102) are likely synergistic to gene therapies focused on dystrophin restoration (akin to the use of corticosteroids broadly in the DMD cohort, albeit with a more targeted and more tolerable/safe approach). Nothing has changed in how we view the end competitive landscape for ATL1102 at this point in time.

CAP-1002 the only non-ambulatory 'competitor' after a recent Phase III fail. We have profiled Capricor Therapeutics' CAP-1002 cell therapy before and continue to note it as the most advanced potential competitor to ATL1102 in the non-ambulatory DMD space with the same focused primary endpoint of PUL2.0. CAP-1002 has entered into a pivotal Phase III trial (HOPE-3) in both ambulatory and non-ambulatory boys with first patient dosed in July 2022, with expected top-line data late 2024/2025. We watch this keenly, noting that cell therapies carry with them manufacturing and safety challenges. FibroGen's PAMREVLUMAB was the other primary late-stage non-ambulatory focused asset of interest, which has just recently reported top-line data from their Phase III trial. It has missed the primary PUL2.0 trial endpoint removing it from our competitor pipeline. Further trial data is expected later in 3Q 2023.

1H 2024 a focus with trial now underway. The past 6 and next 6 months were always going to be quiet for ANP on the news front as they work behind the scenes to execute on their EU Phase IIb trial. We see sites now open in Turkey with Australia, UK and Bulgaria to come online in the coming weeks/months. First patient dosing is complete and ANP noted that interim readout is still expected mid-2024 (a slight delay from initial expectations owing to regulatory delays out of their control). A positive interim read from this study next year is the key catalyst for stock re-rate.

Earnings implications. No changes.

Investment view. No changes.

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For more information please phone: 1300 655 015 or email: publications@wilsonsadvisory.com.au