WILSONS

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Theme Alert

Sector Healthcare

Company

Clarity Pharmaceuticals (CU6)

First look at ^{67}Cu therapy data

Recommendation OVERWEIGHT

12-mth target price (AUD) $1.22

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Announcement Highlights

Clarity have provided an update regarding their SeCuRE trial – the PSMA theranostic trial assessing the identification and treatment of metastatic, castrate-resistant prostate cancer (mCRPC) using Clarity's ^{64}Cu/^{67}Cu-SAR-bisPSMA targeted copper theranostic (TCT) pair. The release of the early data reveal is positive – there were no safety issues reported with ^{67}Cu (at a 4GBq dose level), meaning that the trial can progress to Cohort 2 (utilizing an 8GBq dose). Importantly, even with the lower dose used in Cohort 1, there is already evidence of clinical benefit. As a reminder, this is the first in-human data that demonstrates safety, as well as early clinical utility, of ^{67}Cu, which presents as an important validation and proof of concept point for Clarity. Unlocking ^{67}Cu for therapeutic applications has far-reaching, positive implications.

Wilsons' View

Initial analysis

Cohort 1 completion identifies no safety issues with ^{67}Cu. Clarity confirmed there were no dose-limiting toxicities associated with ^{67}Cu in Cohort 1 patients (n=6) whom received a single administration of 4GBq of ^{67}Cu-SAR-bisPSMA. This is important as it represents the first safety data provided for ^{67}Cu-SAR-bisPSMA, and hence in the prostate cancer population. Additionally, it provides a potential positive read-through for the ongoing trial in neuroblastoma, which is currently assessing a higher dose of ^{67}Cu-SARTATE (0.275MBq/kg, ~3MBq, based on average weight of ~2-year-old patients) in a Cohort 3 expansion. Based on this safety data, Clarity are now able to progress the SeCuRE trial into Cohort 2, whom will receive two administrations of ^{67}Cu-SAR-bisPSMA, or the equivalent of 8GBq.

Early look at ^{67}Cu-SAR-bisPSMA's efficacy is promising. As a reminder Clarity's PSMA therapy product, ^{67}Cu-SAR-bisPSMA, differs from others in development (i.e.TLX-591, PNT2002) and on the market (PLUVICTO), by utilising two PSMA targeting molecules, instead of one. This approach was taken by Clarity, as theoretically, and through early data, they demonstrated superior (2-3x) tumour uptake vs a single PSMA targeting molecule. The data released today provides the first early, in-human evidence that tumour uptake is achieved. At a recognised, low dose of 4GBq (for context PLUVICTO recommends 7.4GBq), clinical benefits were observed in some patients. In one patient, there was a reduction of >50% in PSA levels 48 hours after a single 4GBq administration. This is a focal point given this measure (being PSA level reduction) represents one of the primary endpoints in the SeCuRE trial, and will likely represent an endpoint in a future pivotal trial (if SeCuRE is deemed successful). We expect to see broader clinical benefit with higher dosing (i.e. 8MBq dose in Cohort 2).

SeCuRE trial recap and future development. SeCuRE has been designed as a Phase I/IIa trial comprising; dosimetry-finding, dose escalation and cohort expansion sub-phases. The trial is targeting total enrolment of 44 participants, with an aim to decide on the recommended dose level, the frequency of administration (likely 2-3) and, most importantly the safety and efficacy of ^{67}Cu-SAR-bisPSMA at these levels. We anticipate that the trial will conclude ~end of CY24. We understand that there has been increased urgency placed on this trial (from an investigator/ patient perspective), following the ongoing PLUVICTO supply issues, which will likely drive faster than anticipated recruitment. In April, Clarity's exclusive ^{67}Cu production partner, NorthStar, provided an update regarding the anticipated availability of ^{67}Cu "within a few weeks". The imminent confirmation of this supply is clearly a significant de-risking point for Clarity for future, larger clinical trials, and product commercialisation.

Earnings implications

None. We maintain our current risking on the ^{67}Cu-SAR-bisPSMA program until complete topline data are available (end ~CY24).

Investment view

We maintain our OW rating and $1.22/sh PT on Clarity Pharmaceuticals.

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