

## More positive data SECuREd

Recommendation

OVERWEIGHT

### Announcement Highlights

Clarity have announced further positive data from their ongoing Phase I/IIa theranostic trial in mCRPC with <sup>64</sup>Cu-/<sup>67</sup>Cu-SAR-bisPSMA. Dosing of the therapeutic agent (<sup>67</sup>Cu) at the highest dose of 12GBq has now been completed with no dose-limiting toxicities in Cohort 3 (n=6) allowing Clarity to progress straight into Cohort 4 with a multi-dose of 12+12GBq (2 cycles). The impressive initial responses following a **single dose** of the Tx agent have continued, in this case in high pre-treated patients (5.5 median lines of prior therapy) with impressive PSA declines (27% of patients >80% decline post a single dose). This data of course continues to mature and it is too early to accurately compare to approved therapy responses (for reference PLUVICTO: 6 cycles every 6 weeks, PSA50 46.0%), however these early signs (yet to reach near maximum dosing) continue to support our bullish thesis on Clarity's <sup>67</sup>Cu-SAR-bisPSMA asset.

### Wilson's View

#### Initial analysis

**Totality of Cohort 2 and Cohort 3 data.** The completion of Cohort 3 signifies the end of the single ascending dose study phase of SECuRE, with Cohort 4 expanding into multi-dose phase (2 cycles of 12GBq, n =6). Taking the totality of the data from both Cohort 2&3, impressively, Clarity have managed to achieve PSA declines of ≥50% in at least 44% of patients (technically ≥80%), albeit with a small sample size, n= 9 (**Figure 1**). We note there are an additional 3 of these 9 patients with a ≥35% PSA decline that could contribute to lifting this 44% response rate (but data does not elucidate their relativity to the 50% PSA decline threshold, which is a primary endpoint for SECuRE and a secondary endpoint in key RLT trials - VISION, SPLASH). This is despite the fact that patients only have only received ~10.7GBq (weighted average) in a single dose format (noting we exclude EAP multi dosing responses here). For reference, at this stage Clarity expect to dose 4 cycles of 12 GBq, in a pivotal trial, and therefore the upcoming Cohort 4 data (12+12GBq dosing) will be the most meaningful as to guiding to future efficacy.

**Figure 1: Summary of results from SAD (single dose only) SECuRE Cohorts 1-3**

	n	PSA decline ≥50%	%
Cohort 1- (4 GBq)	6	1	17%
Cohort 2 - (8 GBq)	3	2	67%
Cohort 3a - (12 GBq)	3	1	33%
Cohort 3b - (12 GBq)	3	1	33%
Cohorts 2&3	9	4	44%

NOTE: we assess 4GBq was 'underdosing' of patients and not relevant to end efficacy assessments.

Source: Clarity Pharmaceuticals, Wilsons Advisory.

**Safety data.** From Cohorts 1-3 (n=15), adverse events (AEs) were reported in 8/15 patients (all grades). Three patients (20%), had Grade 3 AEs, the most common (13%) being anaemia. Through the EAP, we note that two patients have received 2, and 4 cycles of <sup>67</sup>Cu-SAR-bisPSMA (achieving 99.4% and 93.7% PSA reduction respectively). The patient whom had received 4 cycles experiences no AEs, whilst the patient receiving 2 cycles, experienced mild or moderate AEs, including dry mouth, altered taste and fatigue which required no treatment and resolved over time (no time specified).

#### Earnings implications

Further de-risking potential of our PSMA Tx asset modelling.

#### Investment view

Under review. Maintain O/W, with risked PT of \$2.78/sh under review.

#### Wilson's Advisory Equity Research

Analyst(s) who owns shares in the Company: n/a Issued by Wilsons Advisory and Stockbroking Limited (Wilsons Advisory) ABN 68 010 529 665 – Australian Financial Services Licence No 238375, a participant of ASX Group and should be read in conjunction with the disclosures and disclaimer in this report. Important disclosures regarding companies that are subject of this report and an explanation of recommendations can be found at the end of this document.

#### Dr Melissa Benson

[melissa.benson@wilsonsadvisory.com.au](mailto:melissa.benson@wilsonsadvisory.com.au)

Tel. +61 2 8247 6639

#### Dr Shane Storey

[shane.storey@wilsonsadvisory.com.au](mailto:shane.storey@wilsonsadvisory.com.au)

Tel. +61 7 3212 1351

#### Madeleine Williams

[madeleine.williams@wilsonsadvisory.com.au](mailto:madeleine.williams@wilsonsadvisory.com.au)

Tel. +61 3 9640 3834

# Disclaimers and Disclosures

## Recommendation structure and other definitions

Definitions at [wilsonsadvisory.com.au/disclosures](https://wilsonsadvisory.com.au/disclosures).

## Analyst certification

Each analyst of Wilsons Advisory and Stockbroking Limited (ACN 010 529 665: AFSL 238375) ("Wilsons Advisory") whose name appears in this research certifies that (1) the recommendations and opinions expressed in this research accurately reflect the analyst's personal, independent and objective views about any and all of the subject securities or issuers; (2) no part of the analyst's compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed by the analyst in the research; and (3) to the best of the analyst's knowledge, he/she is not in receipt of material non-public information about the issuer.

## Disclaimer

This document has been prepared by Wilsons Advisory. This communication is not to be disclosed in whole or part or used by any other party without Wilsons Advisory's prior written consent. All material presented in this document, unless specifically indicated otherwise, is under copyright to Wilsons Advisory. None of the material, its content, nor any copy of it, may be altered in any way, transmitted to, copied or distributed to any other party, without the prior express written permission of Wilsons Advisory. This document is not directed to, or intended for distribution to or use by, any person or entity who is a citizen or resident of or located in any locality, state, country or other jurisdiction where such distribution, publication, availability or use would be contrary to law or regulation or which would subject Wilsons Advisory to any registration or licensing requirement within such jurisdiction.

This document is being supplied to you solely for your information and no action should be taken on the basis of or in reliance on this document. To the extent that any information prepared by Wilsons Advisory contains any financial product advice, it is general advice only and has been prepared by Wilsons Advisory without reference to your objectives, financial situation or needs. You should consider the appropriateness of the advice in light of your own objectives, financial situation and needs before following or relying on the advice. You should also obtain a copy of, and consider, any relevant disclosure document before making any decision to acquire a financial product. Please refer to Wilsons Advisory's Financial Services Guide for more information: [wilsonsadvisory.com.au/disclosures](https://wilsonsadvisory.com.au/disclosures). Any person, before acting on any advice contained within this communication, should first consult with a Wilsons Advisory investment adviser to assess whether the advice within this communication is appropriate for their objectives, financial situation and needs. Those acting upon such information without advice do so entirely at their own risk.

This document provided by Wilsons Advisory is current as at the date of the issue but may be superseded by future publications. Wilsons Advisory assumes no obligation to update the information or advise on further developments relating to the company or companies covered in this document ("Companies") or relevant financial products. Wilsons Advisory has not independently verified all of the information given in this document which is provided at a point in time and may not contain all necessary information about the Companies. Wilsons Advisory makes no warranty, express or implied, concerning any information prepared by Wilsons Advisory. Wilsons Advisory expressly disclaims (1) any implied warranty of merchantability or (2) fitness for a particular purpose, including any warranty for the use or the results of the use of any information prepared by Wilsons Advisory with respect to their correctness, quality, accuracy, completeness, reliability, performance, timeliness, or continued availability. Wilsons Advisory's research content should be viewed as an additional investment resource, not as your sole source of information. To the fullest extent permitted by law Wilsons Advisory, its related bodies corporate and their respective officers, directors, employees or agents, disclaim any and all liabilities for any loss or damage howsoever arising in connection with the use of this document or its contents. Past performance does not necessarily indicate a financial product's likely future performance.

This document may contain "forward-looking statements". Forward-looking statements, opinions and estimates provided in this document are based on assumptions and contingencies which are outside the control of Wilsons Advisory and are subject to change without notice (including but not limited to economic conditions, market volatility and company-specific fundamentals), and therefore may not be realised in the future.

This report does not constitute an offer or invitation to purchase any securities and should not be relied upon in connection with any contract or commitment whatsoever.

# Disclaimers and Disclosures

## **| Regulatory disclosure**

Wilsons Advisory restricts research analysts from trading in securities for which they write research. Other Wilsons Advisory employees may hold interests in the company, but none of those interests are material. Wilsons Advisory further advises that at the date of this report, neither Wilsons Advisory and Stockbroking Limited or Wilsons Corporate Finance Limited have any material interests in the company. This report is part of the ASX Equity Research Scheme FY24 whereby a fee has been paid to Wilsons by ASX Operations Pty Limited (ASX) for the publication of research on Clarity Pharmaceuticals (Company, Clarity). Wilsons maintains that the independence of the research written in this report remains intrinsic to the research published and the ASX is not involved in the compilation of this report. All prescribed ratings and target prices in the report have been influenced by neither the ASX, nor the Company. The research analyst compiling this research has not been directly compensated by the ASX in the production of this research and the analyst attests to the objectivity and independence of the research written.

Wilsons Advisory and Stockbroking Limited may have a conflict of interest which investors should consider before making an investment decision. Wilsons Advisory and Stockbroking Limited, Wilsons Corporate Finance Limited and its related bodies corporate trades or may trade as principal in the securities that are subject of the research report. Wilsons Advisory further advises that at the date of this report, neither Wilsons Advisory and Stockbroking Limited or Wilsons Corporate Finance Limited have any material interests in the company. Wilsons Advisory restricts research analysts from trading in securities for which they write research. Other Wilsons Advisory employees may hold interests in the company, but none of those interests are material.

## **| Wilsons Advisory contact**

For more information please phone: 1300 655 015 or email: [publications@wilsonsadvisory.com.au](mailto:publications@wilsonsadvisory.com.au)