Clinuvel Pharmaceuticals CUV.AX CUV AU

HEALTH CARE & PHARMACEUTICALS

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EQUITY RESEARCH

Vitiligo journal article released

Quick Note

October 16, 2012

Rating Remains	**Buy**
Target price Remains	AUD 3.38
Closing price October 15, 2012	AUD 1.61

Summary

Preliminary observations from CUV's open-label Phase IIa US pilot trial of its drug, afamelanotide, in four patients with Vitiligo (a de-pigmenting skin disease) have been published in the journal *Archives of Dermatology*. In total, 56 patients are participating in the trial, with results from the six-month treatment period expected to be released before the end of CY12.

In all cases, patients' lesions repigmented within the six-month treatment period, with 50-90% overall repigmentation reported. Whilst analyses of the entire study is needed to draw further conclusions, we believe that if an eventual maximum of 10% of US and EU patients were to use afamelanotide, the total CUV NSV opportunity is worth AUD7.62/share. At the current clinical stage, this translates to a risk-weighted NPV of AUD1.63/share for CUV from Non-segmental Vitiligo (NSV).

Background

There are two main types of Vitiligo, unilateral (often called "segmental") and bilateral (usually termed "generalised"):

- **Bilateral, non-segmental or generalised Vitiligo**: this can begin at any age and tends to progress intermittently over the life of the patient. It produces depigmentation that is symmetrical in distribution. This is c80% of all cases of Vitiligo; and
- **Unilateral (segmental) Vitiligo**: this more commonly begins in children and young adults and progresses for a limited period, usually 1–2 years, and then remains static for the life of the individual. It affects just one side of the body. This is c20% of all cases of Vitiligo.

Typically, bilateral Vitiligo progresses over the life of the individual, so that the person has partially normal and partially depigmented skin.

What is the current treatment for Vitiligo?

There are a number of treatments for Vitiligo – the standard treatment is Narrow Band-UVB phototherapy. For repigmentation to occur, it is currently thought that it is necessary that stem cell melanocytes in the hair follicle bulge become stimulated with appropriate signals. CUV believes that afamelanotide may act to augment Narrow Band-UVB phototherapy.

Size of opportunity

NSV affects c10mn persons in the US and EU. CUV's afamelanotide is being evaluated as a combination therapy with narrowband UVB light therapy in two clinical studies in patients with NSV. We believe the NSV market currently USD1.4bn pa, consisting of generic treatments and UVB. We believe the current lack of high-margin branded pharma treatments in the Vitiligo market could mean that should it be approved, then CUV's afamelanotide would be of interest to established dermatology companies, because these companies have salesforces

Research analysts

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See Appendix A-1 for analyst certification, important disclosures and the status of non-US analysts.

and associated infrastructure that already detail product to dermatologists.

The article

The article describes four patient case studies from CUV's CUV102 trial, where afamelanotide is being evaluated as a combination therapy for Vitiligo with narrowband ultraviolet B (NB-UVB) phototherapy, compared to NB-UVB as monotherapy.

The four patients (Fitzpatrick skin types III-VI) published in the Archives article, received four doses of afamelanotide alongside NB-UVB therapy over six months. In all cases, patients' lesions repigmented within the six month treatment period, with 50-90% overall repigmentation reported. The three patients with darker skin types (Fitzpatrick V-VI) saw no relapse of their repigmentation at their three-month follow-up, whereas the lighter-skinned patient (Fitzpatrick III) saw 10% relapse (repigmentation).

What does it mean for CUV?

Whilst analyses of the entire study is needed to draw further conclusions, we believe that if an eventual maximum of 10% of US and EU patients were to use afamelanotide, the total CUV NSV opportunity is worth AUD7.62/share.

Our risk-weighted valuation for EPP, CUV's other near-term opportunity, is AUD1.75/share. CUV's EU registration dossier for afamelanotide in EPP was submitted on 6/2/12. The EMA should decide whether to approve afamelanotide from 210 to 360 days after complete dossier confirmation. Finally, we enclose a link to a report we have written on CUV's Vitiligo opportunity, called "*Opening up the dermatology market*".

Appendix A-1

Analyst Certification

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Clinuvel Pharmaceuticals	CUV AU	AUD 1.61	15-10-2012	Buy	Not rated	A4,A5,A6

A4 A Nomura Group Company had an investment banking services client relationship with the issuer during the past 12 months.

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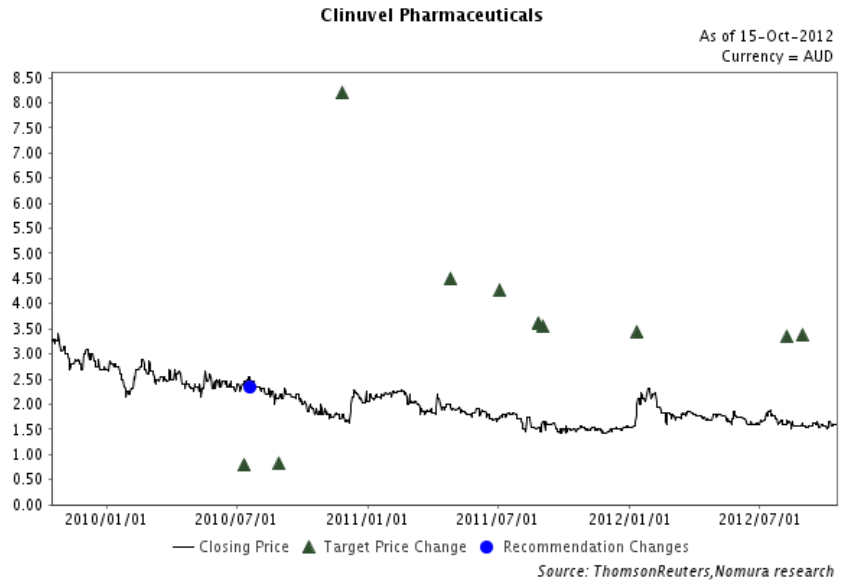
Previous Rating

Issuer name	Previous Rating	Date of change
Clinuvel Pharmaceuticals	Not Rated	12-7-2010

Clinuvel Pharmaceuticals (CUV AU) **AUD 1.61 (15-10-2012)** Buy (Sector rating: Not rated)

Rating and target price chart (three year history)



Date	Rating	Target price	Closing price
29-Aug-12		3.38	1.63
08-Aug-12		3.34	1.69
12-Jan-12		3.44	1.99
02-Sep-11		3.56	1.65
26-Aug-11		3.62	1.54
04-Jul-11		4.26	1.75
26-Apr-11		4.50	2.00
26-Nov-10		8.20	1.80
30-Aug-10		0.82	2.10
12-Jul-10	Buy		2.45
12-Jul-10		0.80	2.45

For explanation of ratings refer to the stock rating keys located after chart(s)

Valuation Methodology Our risk-weighted valuation for EPP is A$1.75/share. Regarding NSV, starting from potential approval in 2016, We believe that if an eventual maximum of 10% of US and EU patients were to use afamelanotide, the risk-weighted NPV for the NSV opportunity for CUV is A$1.63/share. Our risk-weighted valuation of the CUV pipeline (A$3.38) is our TP.

Risks that may impede the achievement of the target price We believe that any delay or failure to progress in clinical trials would present downside risk to our target price. That said, faster-than-expected progression to production of CUV's photoprotective technology could provide an upside boost.

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Explanation of Nomura's equity research rating system in Japan and Asia ex-Japan

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