

March 16, 2012

Rating
Remains **Buy**

Target price
Remains **AUD 3.44**

Closing price
March 15, 2012 **AUD 1.82**

Vitiligo and EPP opportunities progress

Quick Note

Summary

CUV has released: 1) clinically impressive interim Phase II Vitiligo trial results; and 2) US FDA agreement to be allowed to conduct a Phase III study in erythropoietic protoporphyria (EPP). We note that NSV is potentially a large market for CUV, and given positive Phase III EPP trials in the EU, this would lead to a high chance of success for a US Phase III EPP clinical trial, in our view.

1. Clinically impressive interim Phase II Vitiligo trial results presented

Non-Segmental Vitiligo (NSV) is a de-pigmenting disease that affects c10mn persons in the US and EU. CUV's afamelanotide is being evaluated as a combination therapy with narrowband UVB (NB-UVB) light therapy in two clinical studies in patients with NSV. In early Phase II trial results presented at a scientific conference, the NB-UVB plus afamelanotide group provided earlier onset of follicular and/or diffuse repigmentation compared to controls.

What does this mean for CUV?

We continue to believe that treatment of NSV with CUV's afamelanotide could provide an elegant solution to what is a disfiguring disease with a large unmet clinical need. Whilst these are early results, they are impressive clinically, and also go some way to confirming the hypothesis that melanocyte stem cell reservoirs do exist and are clinically relevant in the treatment of Vitiligo. This is helpful, in that it will be necessary to demonstrate mechanism of action of afamelanotide in NSV to gain regulatory approval for afamelanotide. The numbers of persons with NSV in the EU and US are shown in the following figure.

Fig. 1: Number of persons with NSV (EU and US)

(mn)	2012F	2013F	2014F	2015F	2016F	2017F
Northern America	3.1	3.2	3.3	3.4	3.5	3.6
European Union (EU-27)	6.6	6.8	7.1	7.3	7.5	7.7

Source: WHO database, PubMed, Nomura research

We have performed a scenario analysis of the potential NSV opportunity. Starting from potential approval in 2016F, 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 AUD7.73/share. At the current clinical stage, this translates to a risk-weighted NPV of AUD1.65/share from NSV. Please see our previous in-depth report on the NSV opportunity for MSB:

<http://go.nomuranow.com/research/globalresearchportal/getpub.aspx?pid=461148>

2. CUV to conduct a Phase III study in EPP

CUV announced that it had reached an in principle agreement with the US Food and Drug Administration (FDA) to conduct a Phase III study of the novel drug afamelanotide in erythropoietic protoporphyria (EPP).

Research analysts

Australia Health Care & Pharmaceuticals

Dr David Stanton - NAL

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

CUV is currently working to finalise its EPP Phase III study (CUV039) protocol with the FDA following an End-of-Phase-II meeting held on March 12, 2012. After the completion of positive pivotal EU EPP studies in 2011 (CUV029 and CUV030), the expectation is that CUV039 will follow a near-identical design. Pending final comments by the FDA, it is expected that this study will start in May 2012.

High chance of success for a US Phase III EPP clinical trial, in our view

During previous Phase II and III studies in Europe, the US and Australia, afamelanotide has been shown to enable EPP patients to expose themselves to sunlight without incurring characteristic burns (phototoxicity). In December 2011, CUV announced that final analyses of its Phase III European study (CUV029) in EPP showed a clinically relevant, statistically significant prophylactic treatment effect for patients who had been administered afamelanotide.

The key results included:

- Patients receiving afamelanotide reported significantly less pain associated with phototoxicity (median pain score 6.0, $p=0.035$);
- Patients on active drug experienced half as many phototoxic reactions ($p=0.044$);
- Afamelanotide enabled patients to experience significantly more direct sunlight exposure without pain ($p=0.005$); and
- Patients on active drug reported a greater improvement in their Quality of Life (Day 270, $p=0.011$).

Given these strongly positive results in the EU, we would put a high probability of similar results in a US trial.

What is Erythropoietic protoporphyria (EPP)?

EPP is a rare and severe genetic disorder causing absolute UV and light intolerance in the skin. It occurs as a result of an enzyme deficiency that allows for an abnormal build-up of protoporphyrin, a molecule toxic to the body that transforms into excited states on absorption of light energy, causing photo-oxidative damage to the skin. This is manifested through various symptoms such as tingling, stinging, or burning and may accompany the appearance of a rash or blisters. Protoporphyrin build-up also causes general tissue nerve damage that can result in abdomen pain, stomach reflux or, in extreme cases, temporary psychosis. In dealing with the excess protoporphyrin, there is also a high potential for liver damage over time.

The photosensitive effects of EPP can be extremely painful and uncomfortable, often unbearably so. As such, the effect on a patient's lifestyle is normally dramatic. Most patients spend a considerable amount of time and effort avoiding excessive light sources and employing almost complete clothing coverage when possible. Since the photosensitivity results from light in the visual spectrum as well as UV, most sunscreens offer little protection and severe cases may even struggle to find comfort indoors. Ultimately there is no cure for EPP, and limiting light exposure remains the best current treatment option.

Market opportunity for EPP

With no real treatment options for EPP sufferers beyond limiting light exposure, Clinuvel's afamelanotide therapy should prove efficacious. The disease is rare, affecting around one in 60,000-200,000 people worldwide, according to PubMed, although accurate statistics are hard to find. We estimate there are between 7,000 and 14,000 EPP sufferers across the US and Europe. Afamelanotide appears to be one of the few viable treatment options for EPP. CUV has received FDA Orphan drug designation (ODD), allowing for an accelerated review process and certain associated privileges.

Our risk-weighted valuations for the near-term valuations in the CUV pipeline are shown below.

Fig. 2: CUV – Risk-weighted valuation of opportunities

Valuation of CUV R&D portfolio	Risk-weighted valuation (A\$ps)	Risk-weighting (in line with Clincial trial stage) (%)	Total opportunity (A\$ps)
EPP	\$1.78	90%	\$1.98
Non-segmental Vitiligo	\$1.65	21.4%	\$7.73
Valuation	\$3.44		\$9.71

Source: Nomura estimates

CUV is already being reimbursed for its product for EPP in select EU countries, and hence the business model has already been substantially de-risked, in our view.

Appendix A-1

Analyst Certification

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Clinuvel Pharmaceuticals	CUV AU	AUD 1.82	15-3-2012	Buy	Not rated	

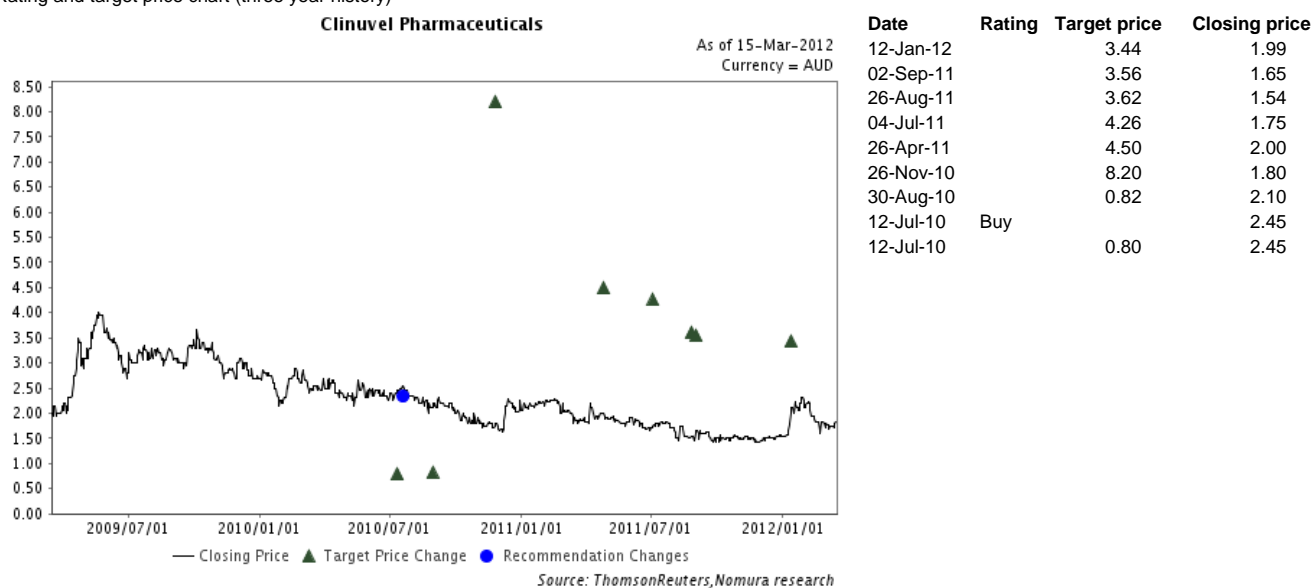
Previous Rating

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

Clinuvel Pharmaceuticals (CUV AU)

AUD 1.82 (15-3-2012) Buy (Sector rating: Not rated)

Rating and target price chart (three year history)



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

Valuation Methodology Our risk-weighted valuation for EPP is A\$1.78/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\$1.65/share. Given the above analysis, we adopt our risk-weighted valuation of the CUV pipeline (A\$3.44) as 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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STOCKS

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

STOCKS

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