Clinuvel Pharmaceuticals CUV.AX CUV AU

HEALTH CARE & PHARMACEUTICALS

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Positive result from pivotal EU Phase III study

Quick Note

December 20, 2011

Rating Remains	**Buy**
Target price Remains	AUD 3.56
Closing price December 19, 2011	AUD 1.50

Research analysts

Australia Health Care & Pharmaceuticals

Dr David Stanton - NAL

Zara Lyons - NAL

CUV announces positive results from pivotal European Phase III study

CUV announced that final analyses of its confirmatory Phase III European study (CUV029) in erythropoietic protoporphyria (EPP) have shown a clinically relevant, statistically significant prophylactic treatment effect for patients who had been administered its alpha-melanocyte stimulating hormone, afamelanotide (16mg controlled-release formulation).

The primary objective of evaluating afamelanotide in EPP patients was to determine whether the prophylactic effect has meaningful clinical benefit. Afamelanotide treatment aims to allow patients to lead a life which includes exposing themselves to ambient light and to engage in outdoor activities. A similar, secondary objective was to assess the effect of treatment on their Quality of Life (QoL).

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).

No safety concerns were identified during the study. Due to the results of this study, CUV is currently finalising a Marketing Authorisation Application (MAA) for afamelanotide for submission to the European Medicines Agency (EMA) within the next few weeks. Approval would allow CUV to market afamelanotide in all 27 European Union member states as well as Norway, Iceland and Lichtenstein.

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

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

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.

What does it mean for CUV?

These are excellent clinical trial results, and should be seen positively by regulatory authorities. We already assumed a positive EPP Phase III clinical trial in our forecasts, and hence this news ties in with our investment thesis. We note that 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. We expect a MAA decision in the EU in 1HCY12.

Fig. 1: 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	$1.91	90%	$2.12
Non-segmental Vitiligo	$1.65	21.4%	$7.73
Valuation	**$3.56**		$9.85

Source: Nomura estimates, Tufts data

Our risk-weighted valuation for EPP is A$1.91/share. For its other opportunity, Non-segmental Vitiligo, starting from potential approval in 2016, we believe that if an eventual maximum of 10% of US and EU patients were to use afamelanotide to treat NSV, the risk-weighted NPV for the NSV opportunity for CUV is A$1.65/share.

Appendix A-1

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Mentioned companies

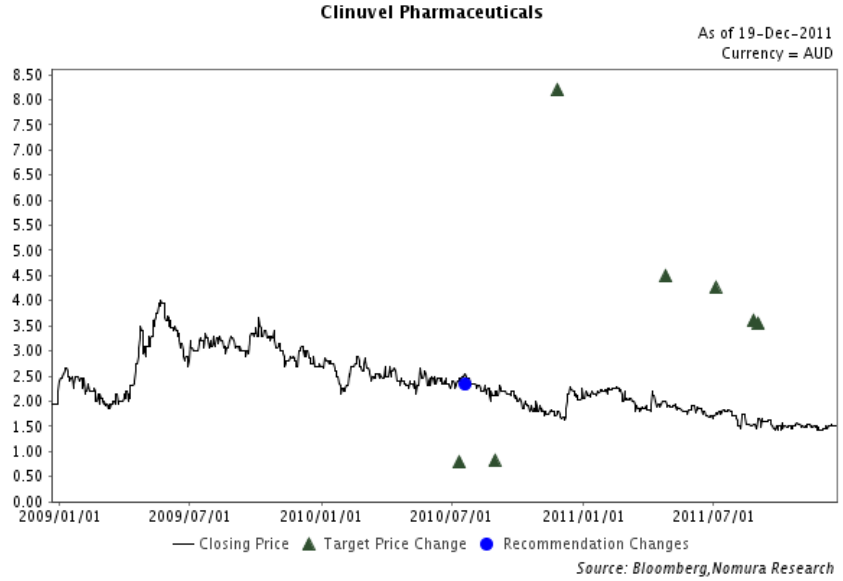
Issuer name	Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
Clinuvel Pharmaceuticals	CUV AU	AUD 1.50	19-12-2011	Buy	Not rated	

Previous Rating

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

Clinuvel Pharmaceuticals (CUV AU) **AUD 1.50 (19-12-2011)** Buy (Sector rating: Not rated)

Rating and target price chart (three year history)



Date	Rating	Target price	Closing price
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$1.91/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$3.56) 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.

Important Disclosures

Online availability of research and conflict-of-interest disclosures

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STOCKS

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Explanation of Nomura's equity research rating system for Asian companies under coverage ex Japan published from 30 October 2008 and in Japan from 6 January 2009

STOCKS

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Explanation of Nomura's equity research rating system in Japan published prior to 6 January 2009

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