Clinuvel Pharmaceuticals CUV.AX CUV AU

HEALTH CARE & PHARMACEUTICALS

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MAA review should complete by start 4QCY12

Quick Note

February 6, 2012

Rating Remains	**Buy**
Target price Remains	AUD 3.44
Closing price February 6, 2012	AUD 2.23

Summary

CUV announced that it has submitted a marketing authorisation application (MAA) for its drug afamelanotide (16mg implant) to the European Medicines Agency (EMA). The MAA covers the use of afamelanotide as a prophylactic treatment in adult patients with erythropoietic protoporphyria (EPP), a rare disease which causes absolute intolerance of patients' skin to light. Approval would allow CUV to market afamelanotide in all 27 European Union member states as well as Norway, Iceland and Lichtenstein. This news is in line with our timelines. We expect a MAA decision in the EU in CY12. The EMA aims to complete a MAA review within 210 days after submission.

High chance of success given positive results from pivotal European Phase III study

In December, 2011, 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.

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

Research analysts

Australia Health Care & Pharmaceuticals

Dr David Stanton - NAL

Zara Lyons - NAL

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

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.

What does it mean for CUV?

We already assumed a 1QCY12 MAA submission 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 CY12. The EMA aims to complete a MAA review within 210 days after submission.

Fig. 1: CUV: Valuation methodology

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, Tufts data

Our risk-weighted valuation for EPP is A$1.78/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

Analyst Certification

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Mentioned companies

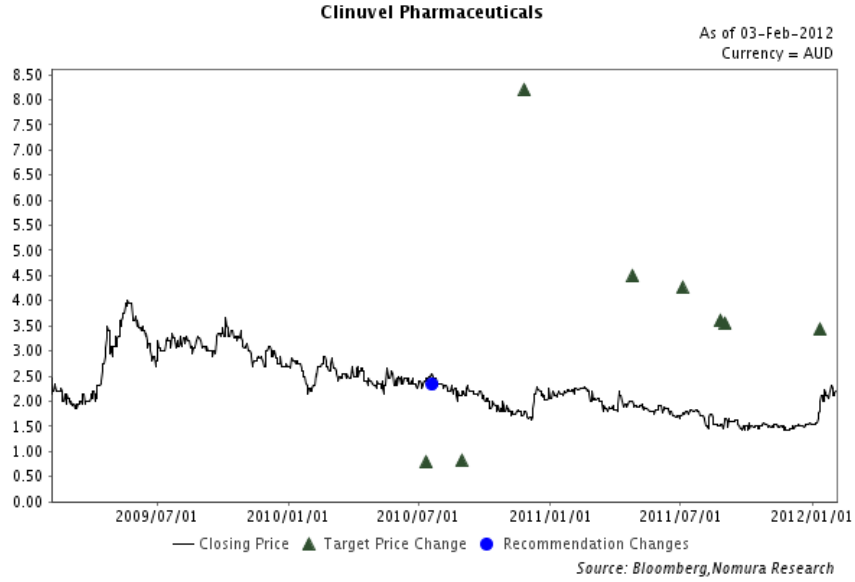
Issuer name	Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
Clinuvel Pharmaceuticals	CUV AU	AUD 2.23	06-2-2012	Buy	Not rated	

Previous Rating

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

Clinuvel Pharmaceuticals (CUV AU) **AUD 2.23 (06-2-2012)** Buy (Sector rating: Not rated)

Rating and target price chart (three year history)



Date	Rating	Target price	Closing price
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$1.78/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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