Clinuvel Pharmaceuticals CUV.AX CUV AU

HEALTH CARE & PHARMACEUTICALS

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Launches US Phase III trial for EPP treatment

Quick Note

May 23, 2012

Rating Remains	**Buy**
Target price Remains	AUD 3.44
Closing price May 22, 2012	AUD 1.61

Summary

Clinuvel Pharmaceuticals (CUV) has started its confirmatory Phase III US study of the novel drug afamelanotide, for the treatment of erythropoietic protoporphyria (EPP), a rare light intolerance disorder. The Phase III trial protocol has been designed in close consultation with the US Food and Drug Administration (FDA). The six-month, randomised, multicentre, double-blind, placebo-controlled study (CUV039) will recruit up to 100 adult EPP patients in seven specialist centres across the US (Alabama, California, Michigan, New York, North Carolina, Texas and Utah). It is expected that the treatment of all patients will be completed before the end of 2012. Should the phase III results confirm the safety and efficacy profiles of afamelanotide as seen in previous trials, then CUV will file a New Drug Application (NDA) for afamelanotide in the US.

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 experienced 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

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

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.

What is the market opportunity for EPP?

With no real treatment options for EPP sufferers beyond limiting light exposure, CUV's afamelanotide therapy may 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 Orphan drug designation (ODD) in the US and EU, allowing for an accelerated review process and certain associated privileges.

In February 2012, CUV submitted a Marketing Authorisation Application (MAA) for afamelanotide for EPP to the European Medicines Agency (EMA). Approval would allow CUV to market afamelanotide in all 27 European Union member states as well as Norway, Iceland and Lichtenstein.

What does it mean for CUV?

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

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	$1.78	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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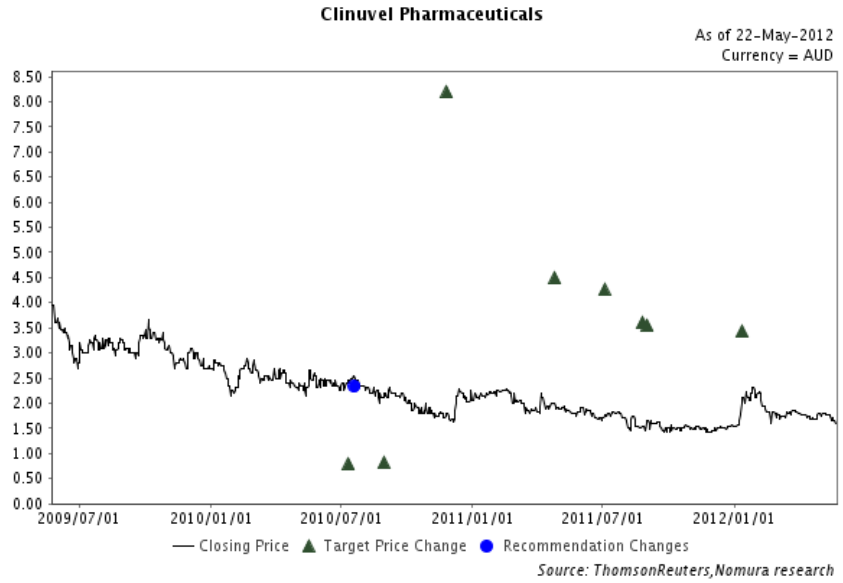
Issuer name	Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
Clinuvel Pharmaceuticals	CUV AU	AUD 1.61	22-5-2012	Buy	Not rated	

Previous Rating

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

Clinuvel Pharmaceuticals (CUV AU) **AUD 1.61 (22-5-2012)** 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. Our risk-weighted valuation of the CUV pipeline (A$3.44) 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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STOCKS

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

STOCKS

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