Clinuvel Pharmaceuticals CUV.AX CUV AU

HEALTH CARE & PHARMACEUTICALS

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Afamelanotide receives approval in Switzerland

Quick Note

April 26, 2012

Rating Remains	**Buy**
Target price Remains	AUD 3.44
Closing price April 24, 2012	AUD 1.67

Afamelanotide receives approval in Switzerland

CUV announced that their afamelanotide product has been accepted by two health insurers in Switzerland for full reimbursement for the prophylactic treatment of patients with erythropoietic protoporphyria (EPP), a rare genetic disease causing extreme intolerance of skin to light. Afamelanotide can be supplied with immediate effect to physicians who treat approximately 50 EPP patients in Switzerland. The costs of supply will be covered in full by the insurance companies.

This is the second country where afamelanotide is fully reimbursed for EPP. The drug has been available on prescription in Italy since 2010. Both countries have allowed supply of the drug under specific laws prior to formal European approval.

CUV awaiting EU approval – this news increases the possibility of EU approval, in our view

In February 2012 CUV filed a marketing authorisation application with the European Medicines Agency (EMA) for EPP. EMA approval would allow CUV to market afamelanotide in all 27 European Union member states as well as Norway, Iceland and Liechtenstein.

The EMA timeline for arriving at a collective decision, and this decision being issued and published by the Committee for Human Medicinal Products (CHMP), normally is between 210 and 360 days after confirmation that a valid application has been received. We believe it is more likely that an orphan drug would receive an opinion at the earlier end of this range.

Italian Law 648/96, Special Access Scheme for EPP – afamelanotide reimbursed

In Italy, the National Regulatory Agency (AIFA) included afamelanotide in May 2010 on the list of reimbursable drugs. Under this law, safety data and patients are collected annually. Every two years, a review of clinical benefit is updated. CUV has negotiated a price of EUR5,375 per injection, given on the basis that patients were eligible for up to six implants annually. On average, we believe Italian patients requested 3.1 implants per year in the first year of eligibility. According to company data, 51 patients received CUV's afamelanotide product, leading to revenues of cUSD1mn.

What does this mean for CUV?

We believe this significant for a number of reasons. Firstly, it demonstrates that CUV is able to receive reimbursement for a new drug entity. Second, the ongoing nature of this programme demonstrates the requirement for the product on a chronic basis. Third, we believe the EMA is likely to take the Italian and Swiss programme into account when making its decision regarding reimbursement on an EU-wide basis. Finally, the ongoing nature of the programme adds to safety data for the treatment.

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.

Background – EPP

CUV has succeeded in enrolling a large number of patients into its EPP trials, considering the rarity of this disease. This may be an indication of the potential patients' willingness to participate, in our view. This is despite the fact that a patient may receive a placebo injection, and hence be subjected to high levels of pain as a part of their disease process. In our view, since high unmet medical need forms a pivotal criterion for the lead regulatory agencies during the evaluation of new therapies, this factor should assist CUV in obtaining approval for afamelanotide.

In early Phase II and Phase III trials, afamelanotide has been shown to mitigate or prevent the symptoms in polymorphous light eruption, solar urticaria, and EPP. These photodermatoses vary in onset, character and severity. CUV has focussed its program on those photodermatoses which are most severe in nature and for which there is no current therapy, like EPP. We enclose the incidence rates for these diseases below.

Fig. 1: Photodermatologic diseases

Disorder	Wavelength (nm)	Symptoms	Prevalence
Polymorphous Light eruption	300-600	Subactute rash, itching, generalised erythema. Transient in spring, diminshing in intensity through summer	10-20% of Caucasian Population, 18% of Europeans
Actinic Prurigo (HLA positive)	300-600	Subacute rash, itching, erythema generalised	Unknown, seen in American Indian and Mexican Popn
Chronic Actinic Dermatitis			16.5 per 100,000
Solar Urticaria	350-550	Acute oedematous reaction, anaphylactic reaction to UV light, most prominent in Spring and Summer	3.1 per 100,000
Discoid Lupus Erythematosis	300-650	Chronic and Recurrent light sensitive episodes of LE on exposed body surfaces	27.7 per 100,000
Erthyropoietic Protoporphyria	408-620	Acute phototoxicity after light exposure	1 per 75,000
Congenital Erythropoietic Porphyria	410		1 per 100,000

Wavelength = corresponds to wavelength of light that at which disease is seen
Source: PubMed, Nomura research

The highest number of patients with EPP is found in the Netherlands, since the disease is thought to be originally of Dutch descent. Approximately 20% of patients are children. Through patient organisations and physician associations, patient registries have been formed and maintained over the last decade. In each of the EU countries, as well as in the US, patient registries are known to each of the National or Regional Porphyria Centres.

Valuation

Our risk-weighted valuations for the near-term opportunities 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, Tufts data

We use our valuation of the CUV pipeline (i.e., AUD3.44) as our target price.

Appendix A-1

Analyst Certification

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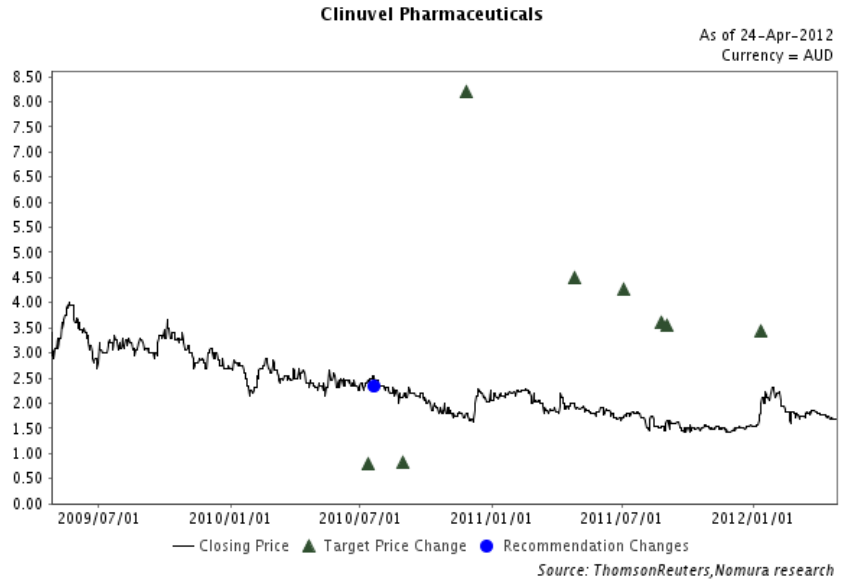
Issuer name	Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
Clinuvel Pharmaceuticals	CUV AU	AUD 1.67	24-4-2012	Buy	Not rated	

Previous Rating

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

Clinuvel Pharmaceuticals (CUV AU) **AUD 1.67 (24-4-2012)** 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

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