Clinuvel Pharmaceuticals CUV.AX CUV AU

HEALTH CARE & PHARMACEUTICALS

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Delay for European EPP decision

Quick Note

April 5, 2013

Rating Remains	**Buy**
Target price Remains	AUD 3.39
Closing price April 4, 2013	AUD 2.35

Research analysts

Australia Health Care & Pharmaceuticals

Dr David Stanton - NAL

Zara Lyons - NAL

Delay for EMA EPP decision

Clinuvel filed its MAA for afamelanotide 16mg implant on 6 February 2012 for the preventative treatment of the orphan light intolerance disorder erythropoietic protoporphyria (EPP). CUV announced that the European Medicines Agency (EMA) has allowed more time to complete the review of CUV's Marketing Authorisation Application (MAA) under the Centralised Procedure. The EMA procedure, led by the CHMP, has had at least a 10-week extension.

We believe the delay is likely to be due to the EMA's need to better understand this treatment for a rare patient population, and this delay is reasonably common in the cases of potential orphan drug approvals for rare diseases. We note that the EMA generally looks at: 1) manufacturing – CUV management previously reported that it had clearing its manufacturing audit in February 2013; and then 2) clinical and other – the clinical discussion is usually through the discussion of the disease treatment with medical Key Opinion Leaders and patient groups. We believe discussions from the EMA may occur in this case to demonstrate the potential importance of this drug to the relevant patient population.

Approval would allow CUV to market afamelanotide in all 27 European Union member states as well as Norway, Iceland and Lichtenstein. To date, four trials in EPP have been completed by the company.

Fig. 1: CUV's EPP clinical trial program

Trial	Phase	Patients enrolled	Study design (months duration)
CUV010	II (EU)	5	Provocation of symptoms by artifical light source (4)
CUV017	III (EU/AU)	101	Cross over study (12)
CUV029	III (EU)	77	2 Parallel arms placebo-active (9)
CUV030	II (US)	74	2 Parallel arms placebo-active (6)
	Total	257	

Source: Company data, Nomura research

Should not delay Vitiligo clinical trials

At 31 December 2012, CUV had AUD9.9mn in cash and marketable securities. We forecast 2HFY13 cash burn of AUD6mn (in part due to ongoing Vitiligo trials, which we expect to continue).

That said, should 2HFY13 cash burn be greater than we expect, this delay in potential earnings from afamelanotide could impact near-term liquidity. We continue to forecast a positive EMA EPP decision, which should lead to strong revenue growth for CUV in FY14F, and this has not changed as a result of this delay.

Background on Phase IIa Vitiligo trial: primary endpoint reached

The primary endpoint was the extent of repigmentation between Day 0 and Day 168 as measured by the VASI and VETF scores (standard scoring methods for Vitiligo). The extent of repigmentation in the

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

afamelanotide/NB-UVB group was significantly greater than observed in the NB-UVB-alone group (VASI, p=0.025; VETF p=0.023; 95% CI).

What are the VASI and VETF?

- The Vitiligo Area Scoring Index (VASI) recording system is a quantitative clinical tool that is used to evaluate Vitiligo and responses to treatment. Basically, the body is divided into five separate and mutually exclusive regions: hands, upper extremities (excluding hands), trunk, lower extremities (excluding the feet), and feet. At each follow-up assessment, any macular repigmentation is noted, and the extent of residual depigmentation within each affected patch that had been present at baseline is estimated to the nearest of one of the following percentages: 0, 10%, 25%, 50%, 75%, 90%, or 100%. The total body VASI is calculated by considering the contributions of all body regions.
- The Vitiligo European Task Force (VETF) recording system is a quantitative clinical tool that is used to evaluate Vitiligo and responses to treatment. Staging is based on cutaneous and hair pigmentation, and the disease is staged 0–4 on the largest macule in each body region, except hands and feet, which are assessed separately and globally as one unique area. Assessment of spreading is based on Wood's lamp examination of the same largest macule in each body area.

Apart from achieving its primary endpoint, here were a number of other interesting points to note from the trial result:

- **Treatment completion**: Forty-one (75.9%, n=41) patients completed the treatment. Thirteen patients withdrew due to their inability to comply with the demanding treatment protocol, or, in the case of five patients, due to the intensity of pigmentation experienced. Overall, the combined treatment was well tolerated and no serious drug-related adverse events were reported;
- **May work better in those with darkest skin (i.e. those most affected by the cosmetic aspects of the disease):** As a subset analysis reflected by the VASI scores, significantly better, more complete and deeper repigmentation was observed for those patients with the darkest skin complexion (phototype IV-VI, n=24) who had received the combination therapy compared to those on monotherapy (p=0.046; 95% CI).

What does it mean for CUV?

From here, CUV will undertake a Phase IIb trial likely to be conducted first in Europe and Asia. Starting from potential approval in 2016F, we believe that if an eventual 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 Vitiligo.

Appendix A-1

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Issuer	Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
Clinuvel Pharmaceuticals	CUV AU	AUD 2.35	04-4-2013	Buy	Not rated	A4,A5

A4 The Nomura Group had an investment banking services client relationship with the issuer during the past 12 months.

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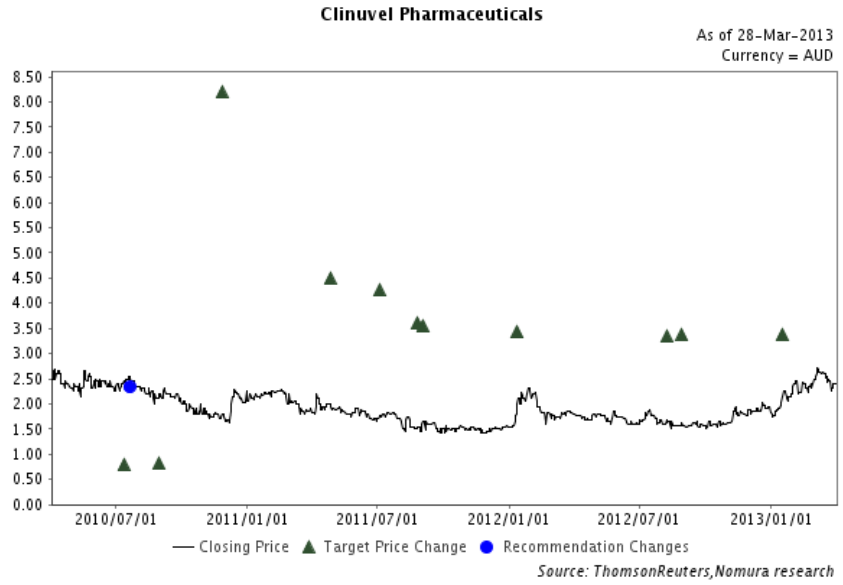
Clinuvel Pharmaceuticals (CUV AU) **AUD 2.35 (04-4-2013)** Buy (Sector rating: Not rated)

Rating and target price chart (three year history)



Date	Rating	Target price	Closing price
16-Jan-13		3.39	2.15
29-Aug-12		3.38	1.63
08-Aug-12		3.34	1.69
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 AUD1.74/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 AUD1.65/share. Our risk-weighted valuation of the CUV pipeline (AUD3.39) 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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Explanation of Nomura's equity research rating system in Japan and Asia ex-Japan

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