

Clinuvel – QuickView

5 January 2012

Event	Phase III results
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Investment summary: Positive in Phase III

Positive results in the second Phase III study of Clinuvel's Scenesse (afamelanotide), a photoprotective drug for treating the orphan condition erythropoietic protoporphyria (EPP), put the drug on track for an EU approval filing, due shortly, and could be a contributory factor in the FDA's decision to conduct a Phase III trial. The data bode well for US/EU study read-outs in the potentially higher-value indication of non-segmental vitiligo (NSV), due in late 2012.

Second positive study allows filing

The 74-patient, EU Phase III study of Scenesse showed significant efficacy in its primary endpoint, pain reduction, with a median pain score of 6.0 ($p=0.035$). It also demonstrated a 50% reduction in phototoxic reactions ($p=0.044$), an increase in the time patients could experience direct sunlight without pain ($p=0.005$), and significant improvement in quality of life. These results pave the way for a filing with the EMA, due soon, and could be instrumental in the FDA's requirement for a Phase III.

Vitiligo indication – potentially more valuable

Confirmation of the drug's efficacy and safety profile is a step closer towards realising its potential in NSV, which has a much higher incidence than EPP. Phase II US/EU pilot studies in NSV are underway to evaluate Scenesse for the activation of melanin production in sufferers (as an adjunct to narrow-band UV light therapy), and early-stage results are due in mid to late 2012.

Well financed

Clinuvel is well financed, with end Q1 cash and short-term investments of A\$14.6m. Approval of Scenesse could improve the outlook, even based on conservative estimates of market penetration, eg, a global market of c 10,000 patients, and based on the price of €32,250 per year as reimbursed under the Italian scheme.

Valuation

The enterprise value based on 2012e net cash of A\$15m is c A\$32m, which leaves potential upside on approval of Scenesse in EPP and news on the vitiligo trial.

Consensus estimates

Year end	Revenue (A\$m)	PBT (A\$m)	EPS (A\$)	DPS (A\$)	P/E (x)	Yield (%)
06/10	1.8	(11.5)	(0.38)	0.0	N/A	N/A
06/11	2.3	(11.4)	(0.37)	0.0	N/A	N/A
06/12e	2.1	(10.6)	(0.29)	0.0	N/A	N/A
06/13e	3.9	(9.2)	(0.22)	0.0	N/A	N/A

Price A\$1.55
Market cap A\$47m

Share price graph



Share details

Code CUV/UR9
Listing ASX/XETRA
Sector Pharmaceuticals & biotech
Shares in issue 30.39m

Business

Clinuvel is an Australian/Swiss biotech company, principally focused on the development of afamelanotide for treating erythropoietic protoporphyria and non-segmental vitiligo.

Bull

- Near-term filing in EPP.
- Phase II US/EU pilot study in vitiligo; results due mid to late 2012.
- Strong balance sheet.

Bear

- 2025 patent expiry on drug delivery implant.
- Threat from counterfeit injectable peptides.
- Potential high price could limit market penetration.

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