

Clinuvel CUV

Short Term (<12m)

Long Term (>12m)

Last Price	Price Target	Risk Rating	Date	Sector
\$00.80	\$01.48	High	24 Jan 07	Healthcare & Biotechnology

Strong Buy Strong Buy

First Australian biotech to receive approval to enter Phase III trial in 2007

Event

Clinuvel has received approval from the UK's Medicines & Healthcare products Regulatory Agency (MHRA) to conduct Phase III trials of its photo-protective drug, CUV1647, for PMLE (Polymorphous Light Eruption), a UV related skin disorder.

Impact

Clinuvel is the first Australian biotech to be granted approval to conduct Phase III trials in 2007.

CUV are arguably now one step closer to commercialisation, discussions with licensing partners and consequent valuation uplift.

We believe CUV offers a better risk profile due to the evaluation of CUV1647's safety and efficacy in over 300 patients.

Overall we see this announcement as a significant positive step for the company and for the share price.

Response

Clinuvel is an Australian biopharmaceutical company, based in Melbourne and San Francisco, focussed on developing its leading drug candidate, photo-protective CUV1647, for a range of UV-related skin disorders resulting from exposure of the skin to the harmful effects of radiation in sunlight.

The approval is two months ahead of schedule and the timing could not be better as we head into Europe's summer. Clinuvel has 10 sites in Europe which have agreed to participate in the P III trials, subject to each site's medical/ethical board approval. We see no obstacles here. Half the sites have been involved in previous trials. European patient and clinic push for a photo-protective drug cannot be underestimated.

This is one of the clinical milestones along its path to registration for up to four registrable clinical indications (AK, PMLE, EPP, SU).



Analyst	Colin Mackie
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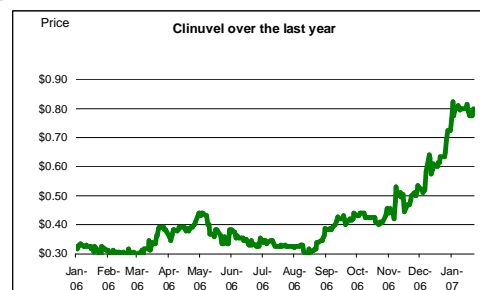
Market Stats		
Market Capitalisation	\$m	221.8
Shares Outstanding	m	277.3
12 Month Price Range	\$0.28 - \$0.83	
Monthly Turnover	\$m	5.4
Monthly Volume	m	7.0
Monthly T'over (of total)	%	17

Forecast Returns		% Return
Forecast Price Appreciation		85.0
Expected Dividend Yield		0.0
Total Forecast Return		85.0

Significant Shareholders		% Held
ANZ Nominees		28.1
Westpac Custodian Nominees		9.0
Merill Lynch		7.0
Kaupthing Bank Luxembourg		4.3

Management		Position
Roger Aston		Exec.Chair
Philippe Wolgen		MD
Dr Helmer Agersborg		Chf Sci Officer

Share Price Chart – 1 Year



Adelaide	Airlie Beach	Cairns	Geraldton	Gold Coast	Maroochydore	Melbourne	Minyama	Mt. Waverley	Perth	Sydney
08 8407 5700	07 4946 5080	07 4046 0220	08 9964 3800	07 5631 2300	07 5409 6100	03 9242 4000	07 5478 1681	03 9831 5000	08 9268 4888	02 9247 8666

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Key Points

This is the first major milestone to be set and met by Clinuvel MD, Philippe Wolgen, since he took over in January of 2006. The milestone has been achieved 2 months ahead of schedule. This is one step closer to licensing discussions and valuation uplift. This is one of four registrable clinical indications which CUV are seeking for its photoprotective drug, CUV1647.

Surprises/Disappointments

This is a very pleasant surprise. It brings forward the timeframe for potential commercialisation, discussions with licensing partners and valuation uplift.

Changes to Our Forecasts

There are no immediate changes to our valuation of \$1.48. We had already factored in a 50% probability for success of the PMLE indication given the quantity and quality of safety and efficacy data.

PMLE background.

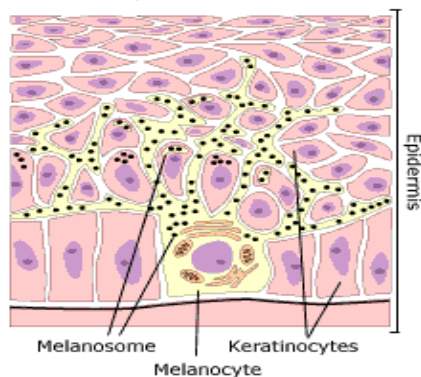
During 2006, Clinuvel successfully conducted a Phase II PMLE trial at St Vincent's Hospital, Melbourne. The trial demonstrated that CUV1647 was able to cause pigmentation of the skin through the induction of eumelanin. As a consequence, patients suffering from PMLE significantly reduced the need to use their usual steroid medication. The trial further endorsed the CUV1647's safety profile and validated the Company's strategy to pursue medical indications for CUV1647.

PMLE market

PMLE has an incidence of approximately 15% of the Caucasian population globally of which 1% are severe and require treatment. Market research indicates 7% of US population, ~25 million people, suffer from PMLE, with up to 10% the cases classified as severe (~3m people). There is currently no prophylactic drug available for PMLE. CUV1647 could provide protection to these patients.

The biology/pharmacology

Alpha-Melanocyte stimulating hormone (α-MSH) is a naturally occurring peptide hormone which is released by cells in the skin in response to stimulation by ultraviolet radiation (UVR) from the sun. MSH has a very short half life (minutes) in the blood stream but does reach and stimulate key cells in the skin (melanocytes) which in turn produce and release melanin/eumelanin, a dark brown pigment that causes darkening (tanning) of skin. Following the administration of CUV1647, melanin remains elevated for several months in the skin, offering protection against UV-radiation. Melanin is known to be photoprotective by acting as a barrier to invisible UV light.



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Drivers/Catalysts

Clinical milestone achievement for the following:

PMLE – approval to conduct PIII trials in 2007.

AK– approval to conduct PII / III trials in 2007.

EPP – orphan indication

SU – orphan indication

Licensing deal indications or announcements for any of the four indications.

Outlook

Short Term

Long Term

This moves Clinuvel from being a project to being a company. The first clinical milestone has been achieved. Investor enthusiasm deserves to lift as CUV is the first Australian biotech to receive approval to conduct PIII trials in 2007.

Clinuvel has globally established a leading position in the area of UV and sun protection. With increased recognition by the public of the damaging effects of UV light and a greater awareness of the potential risk of skin cancer, Clinuvel is well poised to capitalise in this clinical area. We believe this segment will continue to grow commercially over time as increased awareness on environmental changes is of concern to impact health and well being.

Forecasts

Short Term

Long Term

CUV's share price should lift on increased investor interest from Australia and internationally.

On our probability weighted modelling CUV's target medical markets offer sales of \$1.2bn and royalty streams in the target medical market of \$87m. There is tremendous scope for future value creation typical, of the type of returns one sees from profitable specialty pharmaceutical companies with net operating margins in the 25-35% range, after 2009/10.

Valuation

Short Term

Long Term

Our fully diluted NPV sum of parts analysis values the company at \$1.48 per share almost two times the current price. This is based on DCF analysis and using probability adjusted royalty streams and a realistic discount rate of 15%, and long term foreign exchange assumptions.

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Recommendation

Short Term

Long Term

Buy

Buy

Bulls Will Say

New management / clinical direction /strong funding / timeline driven /international partners = ingredients for success

Bears Will Say

The Phase III trial for this indication may yet produce an adverse result.

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In September 2006 Tolhurst accepted a mandate to act for Clinuvel in respect of a capital raising. Shares issued consequent to the capital raising, were listed on the Australian Stock Exchange on the 3rd of November 2006. Tolhurst received fees of approximately \$205,000 in respect of this mandate, some of which will be paid to its Representatives.

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Explanation of Tolhurst Noall's Recommendation and Risk Rating system:

Recommendations are assessments of each Tolhurst Noall Analyst's view of potential total returns over a 1 year period relative to the performance of the All Ordinaries Accumulation Index.

Expected total Return is measured as (capital gain (or loss) + dividend)/purchase price

We have divided our recommendations into five main categories:

Strong Buy: Expected Total Return in excess of 25% over a 1 year period relative to All Ordinaries Accumulation Index

Buy: Expected Total Return between 15% and 25% over a 1 year period relative to All Ordinaries Accumulation Index

Accumulate: Expected Total Return between 5% - 15% over a 1 year period relative to All Ordinaries Accumulation Index

Hold: Expected Total Return between -5% and 5% over a 1 year period relative to All Ordinaries Accumulation Index

Sell: Expected Total Return less than -5% over a 1 year period relative to All Ordinaries Accumulation Index

Risk Ratings:

Risk is a subjective assessment of overall risk within a company including price volatility and earnings variability, external liquidity, and size. We divide our risk into three categories:

High: Company typically has high price volatility and earnings variability, low external liquidity and has a small market capitalisation.

Medium: Company typically has moderate price volatility and earnings variability, external liquidity and a medium size market capitalisation.

Low: Company typically has low price volatility and earnings variability, high external liquidity and is a large size market capitalisation.

Analyst verification

I verify that I, Colin Mackie, have prepared this research report accurately and that any financial forecasts and recommendations that are expressed are solely my own personal opinions. In addition, I certify that no part of my compensation is or will be directly or indirectly tied to the specific recommendation or financial forecasts expressed in this report.

This report has been reviewed by peers within the research department.

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