

Clinuvel Pharmaceuticals

Entering Commercialisation

March 2012 Corporate Update

Stan McLiesh, Chairman
Philippe Wolgen, CEO
Darren Keamy, CFO

ASX: CUV
XETRA-DAX: UR9
ADR: CLVLY



Safe harbor

Clinuvel is an Australian biopharmaceutical company focused on developing its leading drug candidate, afamelanotide, for a range of UV- related skin disorders resulting from exposure of the skin to harmful UV radiation. Pharmaceutical research and development involves long lead times and significant risks.

Therefore, while all reasonable efforts have been made by Clinuvel to ensure that there is a reasonable basis for all statements made in this document that relate to prospective events or developments (forward looking statements), investors should note the following:

- actual results may and often will differ materially from these forward looking statements;
- no assurances can be given by Clinuvel that any stated objectives, outcomes or timeframes in respect of its development program for afamelanotide can or will be achieved;
- no assurances can be given by Clinuvel that, even if its development program for afamelanotide is successful, will obtain regulatory approval for its pharmaceutical products or that such products, if approved for use, will be successful in the market place.

Company overview

- Global biopharmaceutical company focused on the development of drugs for the treatment of a range of severe skin disorders
- Primary focus is the development of SCENESSE, a proprietary drug with a range of applications (nonsegmental vitiligo, erythropoietic protoporphyria (EPP), Actinic Keratosis /Squamous Cell Carcinoma)
- Advanced stage of development for EPP:
 - Applied for authorisation to market SCENESSE for the treatment of 'orphan' skin disease (EPP) throughout Europe following the completion of Phase III clinical studies
 - Reached in principle agreement with the US Food and Drug Administration (FDA) to conduct a Phase III study of EPP

Share register

Top 20	Own 63%
Shareholder mix	Retail – 51% Non-Retail – 49%
Geographic mix	Australia – 49% EU – 33% US / RoW – 18%
USA ADR Program	10%
Staff and management ownership interests	3.8% - 4.3%

Share price performance – last 12 months



Directors

Mr Stan McLiesh, BEd

Non-Executive Chairman, >30 yrs pharma experience – commercialisation, M&A

Mrs Brenda Shanahan, Mr Jack Wood, Mr Elie Ishag

Non-Executive Directors, broad background in finance, healthcare, pharma deal making

Dr Hank Agersborg, BSc, PhD

Chief Scientific Officer & Director, 53 NDA's, most experienced at FDA process

Dr Philippe Wolgen, MD, MBA

Chief Executive Officer, background finance, healthcare analyst, qualified surgeon, raised AU\$68M for CUV

Key management

Dr Dennis Wright, MSc, PhD

VP Scientific Affairs, clinical/regulatory expert EU/US

Mr Darren Keamy, BCom, CPA

CFO, Company Sec, experienced CPA to public companies

Dr Nicoletta Muner, BPharm (Hons)

MPharmSci

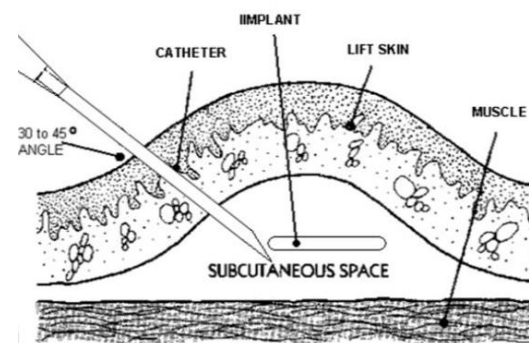
Director, Global regulatory affairs, >15 yrs EU

Ms Daniela Schaefer

VP Business Development, >15 yrs banking/ investment experience

SCENESSE® (afamelanotide)

- An analogue of the naturally occurring melanocortin alpha-MSH
- Unique properties due to optimized chemistry
- Systemic photoprotection, provides filter for light-UV
- First-in-class drug (New Molecular Entity)
- Patented injectable 16mg resorbable formulation
 - Size grain of rice
 - Controlled-release
 - Physician administered
 - Protection for 60 days



Development cycle & milestones '06-'12

Clinical & regulatory

EU Ph II EPP results, approval for EU Ph III¹ EPP trial

Final SCENESSE[®] dose selected

EU Ph III¹ EPP starts,

FDA allows IND

FDA allows EPP Ph II

Vitiligo program starts, EU Ph III¹ EPP results

FDA allows vitiligo Ph II

US Ph II, EU Ph III² EPP results

Finance

Placement A\$5M

SPP A\$0.4M, Placement A\$26M

Rights issue, placement A\$35.2M

Commercial

New management

Italian program starts

SCENESSE[®] brand approval

First A\$1M sales

Manufacturing partner secured



EPP Ph III¹: CUV017 (EU & Aust)
EPP Ph III²: CUV029 (EU)



1st Clinical target: EPP

Erythropoietic protoporphyria (EPP) – absolute light intolerance

Est. global incidence: up to 11,000 assessable patients (4,500 EU/6,500 US)



Phototoxic reaction in EPP

- Rare (orphan) lifelong genetic disorder
- No effective treatment/preventative – high unmet clinical need
- SCENESSE® safe, effective in Phase III trials as photoprotective

Commercial opportunity

- US\$50-100M p/a
- Orphan indication: exclusivity obtained (10 yr EU, 7 yr US)
- European Marketing Authorisation Application filed Feb 2012
- US End-of-Phase II positively concluded with FDA, start of US Phase III May 2012
- Agreed reimbursement program underway in Italy

Italian EPP program – distribution model

- Italian law allows prescription of SCENESSE® to EPP patients, reimbursement for supply by Italian government
- Agreed pharmacoeconomic benefit with national reimbursement agency - €32,250/patient/per annum
- 12 month (2010-2011) sales A\$1m
- Identified patient population and physician network
- Distribution to patient population done in-house using same process established for clinical trials
- This model demonstrates Clinuvel can market SCENESSE® for EPP on its own

Transitioning from R&D to commercial sales

- 1st Marketing Authorisation Application for EPP filed with EMA Feb 2012, decision expected Q4 '12 - Q1 '13
- EU reimbursement discussions underway
- High level global physician and patient support
- Solo distribution versus partnership

2nd Clinical target: vitiligo

Vitiligo – acquired depigmentation disorder

Est. global incidence: 45 million patients



- Progressive, psychologically devastating disease
- No effective treatment to date, high unmet clinical need (FDA)
- SCENESSE® used as combination repigmentation therapy
- First clinical observations impressive (**ASX announcement 15/03/2012**)

Depigmentation caused by vitiligo
Image: courtesy Pearl E Grimes MD

Commercial opportunity

- >US\$600M p/a
- Strong patent protection
- No other systemic pharmaceuticals under development
- High level of support from medical community
- Approvals from regulatory agencies

Observations from vitiligo clinical programs

- Clinical observations presented at leading global dermatology conferences (AAD/EADV)
- Physicians encouraged at speed, depth of repigmentation following afamelanotide implant + NB-UVB treatment vs NB-UVB alone



Day 0 - baseline



Day 55 – 15 treatments
nUVB/1 implant



Day 140 – 32 treatments
nUVB/4 implants

Preliminary Data on 15 HFH Patients

Average Time to Onset of First Repigmentation
(From day 1 of NB-UVB treatment)

	No. Weeks of NB-UVB until repigmentation	No. NB-UVB treatments until repigmentation
Afamelanotide/ NB-UVB (n=8)	5.75 wks	12.25 tx
NB-UVB Only (n=7)	6.7 wks	19.5 tx

	Visit No (day)	Baseline VASI	Current VASI	Difference
Afamelanotide/ NB-UVB (n=8)	4.6 (d 100)	21.5	16.0	5.5
NB-UVB Only (n=7)	4.7 (d 103)	26.2	21.5	4.7

Prospective markets

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India

- Estimated >10M vitiligo patients
- National healthcare system
- Vitiligo recognised as national healthcare priority
- High level NB-UVB penetration

USA - EPP

- 6,500 EPP patients

EU - EPP

- 4,500 EPP patients

USA - vitiligo

- Up to 6M vitiligo patients
- Insurance coverage NB-UVB

Additional Programs Pipeline

Preclinical

Phase II

Phase III

Product: SCENESSE® (afamelanotide)
Polymorphous light eruption (PLE), likened to sun poisoning – EU

Product: SCENESSE® (afamelanotide)
Actinic keratosis and squamous cell carcinoma in transplant patients,
skin cancer in high risk population –EU/AU

Product: SCENESSE® (afamelanotide)
Pediatric dose for EPP

Product: CUV9900
Alpha-MSH analogue in development

Conclusions

- Focussed and committed lean organisation based in 3 continents
- SCENESSE® on track for market registration in erythropoietic protoporphyria (EPP)
 - Orphan drug indication US and EU, no current therapy
 - Positive, statistically significant US Phase II and EU Phase III results
 - EU filing for marketing authorisation Feb 2012
 - Ph III start in USA (FDA permission)
- Near-term commercial opportunities for EPP indication
 - Italian reimbursement and distribution model shows viability for in-house distribution
- Trials underway for unmet needs in larger indications
 - Positive observations from current US Phase II study in vitiligo