Company Announcement

Friday 21st October 2011
Melbourne, Australia

First positive observations from Clinuvel's US vitiligo trial

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that early clinical observations from the company's open label Phase II pilot trial (CUV102) of the novel drug SCENESSE® (afamelanotide) in patients with nonsegmental vitiligo (NSV) were presented at the European Academy of Dermatology and Venereology (EADV) meeting in Lisbon overnight.

Two clinical investigators from the CUV102 study – Dr Henry Lim, Chair of Dermatology at the Henry Ford Hospital, Detroit, Michigan, and Dr Pearl E Grimes, Director of the Vitiligo and Pigmentation Institute of Southern California and Clinical Professor of Dermatology, University of California, Los Angeles – co-presented – during the MSH Society meeting[1] at the EADV – their first observations from a cohort of 21 patients undergoing repigmentation treatment for NSV. Slides from this presentation have been appended.

Phase II study design – CUV102
Under the CUV102 protocol, 50% of the patients enrolled are undergoing repigmentation treatment with narrowband ultraviolet B (NB-UVB) therapy in combination with SCENESSE®, while the remaining 50% are being treated with NB-UVB alone. Cases from both the SCENESSE® and control groups were presented and discussed at the meeting.

The clinical objectives of the CUV102 trial are to determine whether SCENESSE® reduces the total dose of radiation (NB-UVB) and the time required to reactivate skin pigment producing cells (melanocytes) in vitiliginous lesions. NB-UVB clinically administered thrice per week over 18 months is considered the standard of care in NSV to stimulate repigmentation in depigmented skin and prevent the progression of lesions, but it is only partially effective as a standalone therapy.

Initial observations
Early observations in 21 patients showed that monthly dosing of afamelanotide (16mg implant) in combination with NB-UVB has the capacity to achieve accelerated and deeper pigmentation of vitiliginous skin lesions. A number of patients have required less NB-UVB dosing during the course of combination treatment.

These first findings support the scientific premise that melanocytes are able to adequately respond to pharmaceutical therapy with melanisation of the skin in nonsegmental vitiligo. The majority of patients in this first cohort were African-Americans and Hispanic patients (Fitzpatrick skin types IV-VI) who have been diagnosed with NSV within the last five years.

"Our early observations from Los Angeles and proof-of-concept data suggest that afamelanotide speeds up the repigmentation of these patients," Dr Grimes said. "In today's presentation we discussed the pigmentary response that is seen in patients in the days immediately after drug administration. However, definitive answers as to the drug's effectiveness can only be given after further results emerge and completion of this study. If we were to identify a drug which assists the vitiligo patients in their repigmentary process it would be an enormous advantage to patients worldwide."

"The early clinical observations are promising, though we need more data to arrive at definitive conclusions," Dr Lim said. "It seems from these early observations that the drug increases the rate of repigmentation and response time following narrow band UVB. During the continuation of this multi-centre study, we will analyse which type of vitiligo repigments best with combined treatment and which anatomical areas respond the most."

Nonsegmental vitiligo

Vitiligo is a disease in which there is a loss of melanin (pigment) production resulting in white or off-white depigmented skin lesions on different parts of the body. Nonsegmental vitiligo, the most common subtype of the disease, affects more than 45 million patients worldwide. This disorder may spread over time and cause patients significant psychological and emotional distress. The exact cause of vitiligo is unknown, but it is generally accepted that an autoimmune component may play a role in the disease.

Therapy for vitiligo is intended to arrest depigmentation or provide repigmentation of depigmented lesions. Treatment options exist but many clinical challenges persist in the various patient populations. Not all patients respond to available therapies and relapse is common. NB-UVB therapy has emerged as a mainstay therapy for vitiligo, but requires patients to attend clinics 2-3 times a week for up to 18 months, presenting a treatment and cost burden.

The CUV102 study is ongoing across three centres (California, Michigan and New York) in the USA and is expected to be complete in early 2012. A parallel study (CUV101) is under way in Europe across three centres (France, Italy and Switzerland). The two studies, the first in Clinuvel's INSPIRE (**In**ternational **S**CENESSE® **Pi**lot **R**epigmentation **E**valuation) program, will recruit between 80 and 120 patients in total. Interim results from both studies are expected to be announced in the middle of 2012.

– End –

[1] The inaugural Melanocyte Stimulating Hormone (MSH) Society subspecialty meeting was held at the 2011 EADV. Further details can be found at www.eadvlisbon2011.org.

SEE BELOW FOR PRESENTATION SLIDES

Appendix I: Slides presented at the MSH Society meeting, EADV 2011

First Clinical Observations CUV102

STUDY TITLE:

A Proof of Concept Study to Compare the Efficacy and Safety of Subcutaneous, Bioresorbable Afamelanotide Implants and Narrow- Band Ultraviolet B (NB-UVB) Light vs Narrow-Band Ultraviolet B (NB-UVB) Light Alone in the Treatment of Nonsegmental Vitiligo

All images courtesy of the Vitiligo and Pigmentation Institute of Southern California

Images have been cropped to maintain patient privacy but are otherwise unaltered

Thursday October 20, 2011

Dr H Lim, Chair of Dermatology at the Henry Ford Hospital, Detroit, Michigan
Dr P E Grimes, Director of the Vitiligo and Pigmentation Institute of Southern California

Study objectives CUV102

Evaluate SCENESSE® (afamelanotide 16mg) in combination therapy for nonsegmental vitiligo

to demonstrate whether SCENESSE® is, in a safe manner, able to:

- induce deeper and faster repigmentation
- reduce the NB-UVB dose
- induce follicular repigmentation

CUV102 Los Angeles 2011

NB-UVB monotherapy

Patient has phototype VIa (Fitzpatrick classification)

DAY 0 – before start of treatment
Near-complete peri-orbital depigmentation treated with NB-UVB thrice per week

DAY 23 – after 9 NB-UVB treatments
Pigmentary changes seen at glabellar region, suborbital and nasal bridge

DAY 59 – after 20 NB-UVB treatments
Continuous repigmentation seen, most pronounced on upper eyelids, left suborbital and right side of nasal bridge

DAY 112 – after 33 NB-UVB treatments
Further repigmentation bilateral suborbital areas

All images courtesy of the Vitiligo and Pigmentation Institute of Southern California
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CUV102 Los Angeles 2011

NB-UVB/afamelanotide combination

Patient has phototype VIb (Fitzpatrick)

DAY 0 – before start of treatment
Near-complete peri-orbital depigmentation treated with NB-UVB thrice per week and afamelanotide starting after 12 sessions NB-UVB

DAY 35 – after 15 NB-UVB treatments and 1st afamelanotide 16 mg implant (Day 29)
Follicular repigmentation seen at upper eyelids

FOLLICULAR REPIGMENTATION

DAY 51 – after 22 NB-UVB treatments and 2nd afamelanotide 16 mg implant (Day 51)
Continued follicular repigmentation seen on upper eyelids

DAY 66 – after 29 NB-UVB treatments and 2nd afamelanotide 16 mg implant (Day 51)
Near-complete repigmentation bilateral peri orbital areas and upper eyelids

All images courtesy of the Vitiligo and Pigmentation Institute of Southern California
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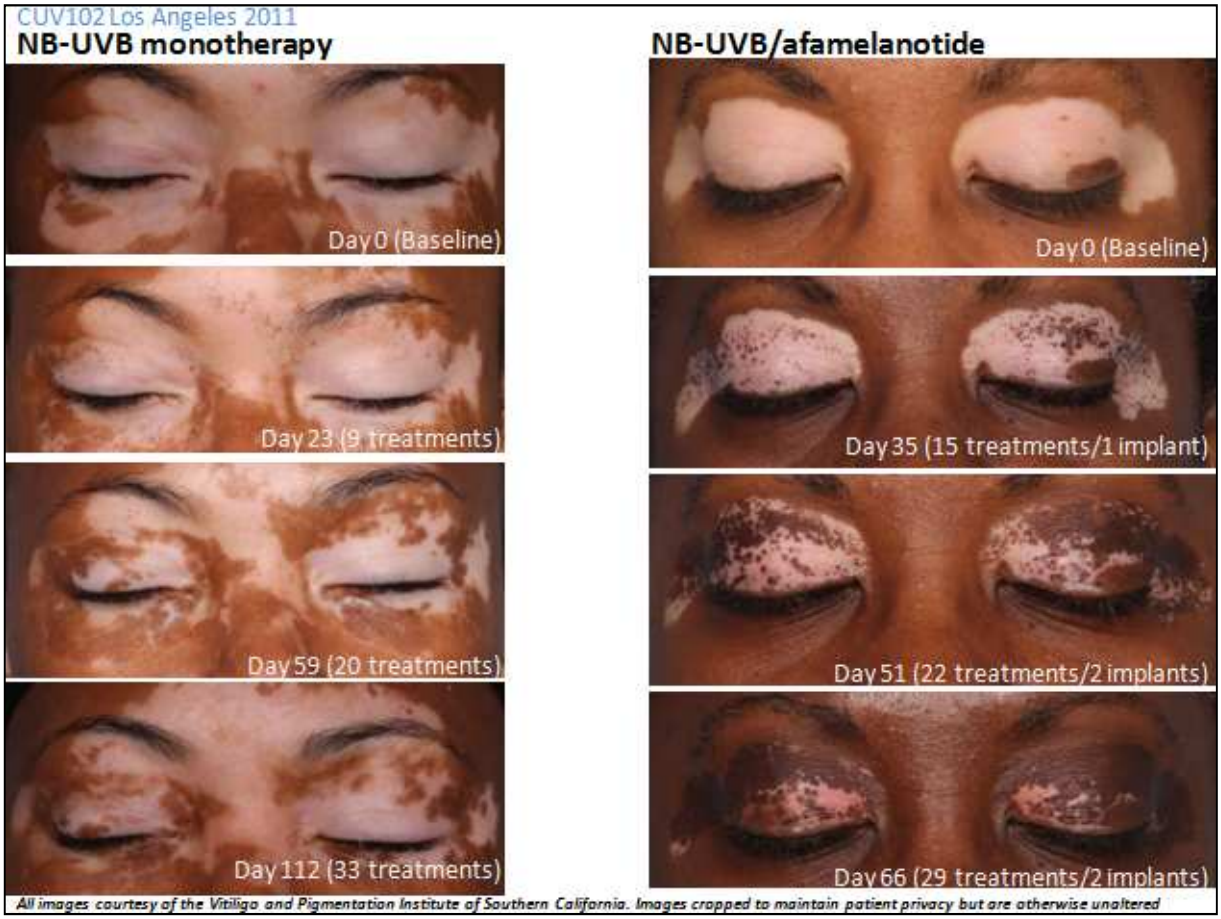
CUV102 Los Angeles 2011



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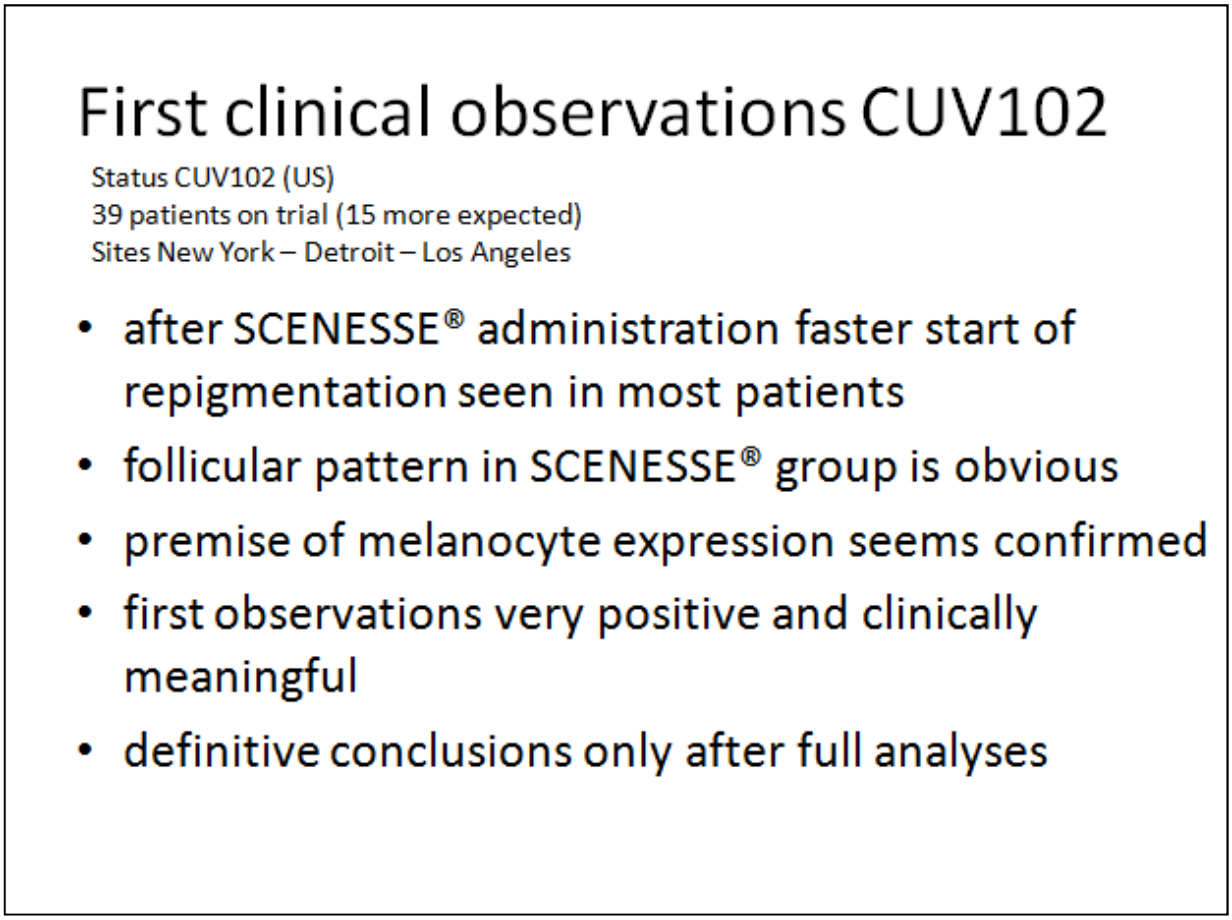
COMPARISON OF 2 PATIENTS WITH DEPIGMENTED PERI-ORBITAL AREAS

COMPARISON	NB-UVB	COMBI	DIFFERENCE
Days treated	91	68	-23
Sessions	27	30	3
Cum Dose head	9650	8652	-10.3%



Appendix II: About SCENESSE®
SCENESSE® (afamelanotide) is a first-in-class dermatological drug being developed solely by Clinuvel. The active ingredient in SCENESSE® is afamelanotide, a chemical analogue of α-MSH which activates melanin in the skin and so shields the patient against UVR and sunlight. SCENESSE® is delivered as a subcutaneous, dissolving implant approximately the size of a rice grain.

About Clinuvel Pharmaceuticals Limited
Clinuvel Pharmaceuticals Ltd (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) is a global biopharmaceutical company focused on developing drugs for the treatment of a range of severe skin disorders. With its unique expertise in understanding the interaction of light and human skin, the company has identified three groups of patients with a clinical need for photoprotection and another group with a need for repigmentation. These patient groups range in size from 10,000 to 45 million. Clinuvel's lead compound, SCENESSE® (afamelanotide), a first-in-class drug targeting erythropoietic protoporphyria (EPP), is in Phase II and III trials in the US and Europe, and is expected to be filed before the end of 2011 for review by the European Medicines Agency. Based in Melbourne, Australia, Clinuvel has operations in Europe and the US. For further information please visit www.clinuvel.com

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