Company announcement

Wednesday 15th July 2009
Melbourne, Australia

Clinuvel announces positive results in Phase II Solar Urticaria study

Afamelanotide: a novel photoprotective drug in severe light allergy

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced positive results from an open-label Phase II study in the severe rare skin disorder Solar Urticaria (SU), conducted at Manchester Hope Hospital UK. In a pilot study of 5 patients, the efficacy of afamelanotide was evaluated as a preventative photoprotectant in this disease.

The objectives of the study were to test the efficacy of subcutaneously administered afamelanotide as a photoprotective drug in patients diagnosed with SU by measuring skin reactions, characteristic 'wheal' formation and tolerance to UV and sunlight.

Solar Urticaria
SU is a skin disorder marked by an acute allergic response following UV or sun exposure. Symptoms can be systemic, such as anaphylaxis, breathing difficulty, nausea and headaches. Immediate localised reactions vary from characteristic 'wheal' formation and erupting flares on exposed skin sites, to swelling of soft tissues. Current available treatment is only partially effective and consists of anti-histamines, immunotherapy and plasmapheresis (blood purification). It is estimated that 3-4 people per 100,000 suffer from SU worldwide.

Orphan Designation
Clinuvel obtained orphan designation from the EMEA in June 2009 to develop afamelanotide for the preventative treatment of SU.

Results
In all patients, the tolerance of the skin to light of various wavelengths and intensities was increased following administration of afamelanotide.

The size and intensity of skin reactions and wheal formation was significantly reduced ($p<0.003$) at 30 and 60 days following dosing of afamelanotide. Importantly, the Minimal Urticarial Dose (MUD), a scientific measurement of tolerance to UV and sunlight in SU, was significantly increased ($p<0.001$) in all patients at 30 and 60 days.

These results indicate that afamelanotide may reduce the risk of incapacitating reactions to UV and sunlight in SU patients.

Clinuvel's Chief Scientific Officer Dr Hank Agersborg said:

"Today's unequivocal results give further support to the use of afamelanotide as a medicinal photoprotective drug in patients who are gravely affected by UV and sunlight. Clinuvel will now accelerate its program in Solar Urticaria worldwide and apply for permission to start Phase III confirmatory controlled trials."

"This outcome, together with the recent interim results (January '09) in our Phase III program in the orphan disease Erythropoietic Protoporphyria (EPP), has made the chances to commercialise our drug realistic and likely."

-End-

Appendix I (Following Code of Best Practice, ASX)

Name of trial
CUV016. A Phase II, Open Label Pilot Study to Evaluate the Safety and Efficacy of A Bioresorbable Subcutaneous Implant of Afamelanotide (CUV1647) in Patients With Solar Urticaria (SU)

Primary endpoints
a) To determine whether an afamelanotide (synthetic alpha-MSH analogue) bioresorbable implant can reduce the susceptibility of patients with Solar Urticaria to provocation with a standardized light source (measured as a change in minimum urticarial dose, (MUD)).

Secondary endpoints
a) To evaluate the safety/tolerability of afamelanotide by measuring treatment-emergent adverse events.
b) To determine the effect of afamelanotide on melanin density at several specified body sites.
c) To evaluate a change in the MUD between Days 30 and 60.

Blinding status
Open label.

Product Development Status
Good Manufacturing Practice (GMP) Standard.

Treatment method, frequency, dose levels
A single implant (16 mg afamelanotide) administered subcutaneously.

Number of trial subjects
5 patients.

Subject selection criteria
a) Male or female subjects with a diagnosis of Solar Urticaria (confirmed by phototesting) of sufficient severity that they have requested treatment to alleviate symptoms;
b) React to provocation with a light source;
c) Aged 18 to 70 years;
d) Fitzpatrick Skin Type I-IV.

Trial location
Single centre trial in Europe at Hope Hospital, Manchester, UK.

Trial standard
In compliance with Good Clinical Practices (GCP) and ICH guidelines.

Appendix II

About afamelanotide
Afamelanotide is an analogue of α-MSH, a peptide which activates the body's natural ability to produce eumelanin, the dark pigment of the skin which is known to offer photoprotective properties, thus providing skin protection against UV radiation (UVR). Increased pigmentation of the skin appears a few days after administration of afamelanotide and lasts up to two months. Afamelanotide is administered underneath the skin as a dissolvable implant approximately the size of a grain of rice.

About Clinuvel Pharmaceuticals Limited
Clinuvel Pharmaceuticals Ltd is a leading and innovative Australian company focused on the development of afamelanotide, its proprietary first-in-class photoprotective drug. Clinuvel has identified five groups of patients with a clinical need for photoprotection. Currently, Clinuvel is in its final stages to complete testing of afamelanotide in Phase II and III trials in Australia and Europe. Clinuvel's ongoing focus is to demonstrate the safety and efficacy of afamelanotide.

Clinuvel is currently testing afamelanotide in five clinical indications:

Indication	Description	Clinical Trial Status
Erythropoietic Protoporphyria (EPP)	Absolute sun/UV intolerance	Phase III trials started April 2007

Polymorphic Light Eruption (PLE / PMLE)	Severe sun/UV poisoning	Phase III trials started May 2007
Actinic Keratosis (AK) and Squamous Cell Carcinoma (SCC) in Organ Transplant Recipients (OTRs)	Skin cancer in transplant patients	Phase II trials started October 2007
Solar Urticaria (SU)	Acute anaphylactic reaction to sun/UV	Phase II trials reported July 2009
Photodynamic Therapy (PDT) - systemic	Phototoxicity following cancer treatment	Phase II trials started September 2008

Phase I and II human clinical trials using afamelanotide have demonstrated that the drug is well tolerated and no significant safety concerns have been identified to date.

Following successful conclusion of the development program, Clinuvel will work closely with global regulators to facilitate marketing approval of afamelanotide.

About Solar Urticaria (SU)
SU is a skin disorder marked by an acute allergic response following UV or sun exposure. Symptoms can be systemic, such as anaphylaxis, breathing difficulty, nausea and headaches. Immediate localised reactions vary from characteristic 'wheal' formation and erupting flares on exposed skin sites to swelling of soft tissues. The wavelengths of radiation causing the SU onset (i.e. the action spectrum) are in the ultraviolet or visible light range. SU may have a very sudden and dramatic onset, and may rapidly disappear once exposure ceases. A delayed form of SU has also been reported.

SU patients typically avoid UV and visible light sources; to prevent outbreaks, they tend to live indoors in social isolation. It is estimated that 3-4 people per 100,000 suffer from SU worldwide. Current available treatment is only partially effective and consists of anti-histamines, immunotherapy and plasmapheresis (blood purification).

Clinuvel obtained orphan designation from the EMEA in June 2009 to develop afamelanotide for the preventative treatment of SU.

For more information contact:

Lachlan Hay
Head of Global Network and Communications
Clinuvel Pharmaceuticals Limited
T: +61 3 9660 4900
E: investorrelations@clinuvel.com
Twitter: @ClinuvelNews

Clinuvel is an Australian biopharmaceutical company focused on developing its photoprotective drug, 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 programme for afamelanotide can or will be achieved;
- no assurances can be given by Clinuvel that, even if its development programme for afamelanotide is successful, it will obtain regulatory approval for its pharmaceutical products or that such products, if approved for use, will be successful in the market place