Company Announcement

Monday 30th November 2009
Melbourne, Australia

The European Medicines Agency (EMEA) grants Clinuvel SME status

Small medium enterprise status ahead of regulatory filings of afamelanotide

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) is pleased to announce today that it has obtained the EMEA status of small and medium enterprise (SME). This status provides incentives to Clinuvel during the preparation for its filing and commercialisation of afamelanotide in Europe.

SME status is granted by the EMEA to assist eligible companies during the pre-marketing authorisation period, Scientific Advice, marketing authorisation application and inspection procedures.

In 2008 and 2009, afamelanotide was given Orphan Drug Designation (ODD) from the EMEA for the treatment of erythropoietic protoporphyria (EPP) and solar urticaria (SU). Afamelanotide is being developed as a photoprotective drug in three additional photodermatoses in Phase III and II trials. Clinuvel intends to file for registration of afamelanotide in Europe, Norway, Iceland and Liechtenstein ahead of other global markets in 2010.

Clinuvel's CEO Dr Philippe Wolgen said: "Our activities are part of a continuum towards European market entry, and the reduced regulatory expenditure as a result of the award of SME status is most welcome. As a result of achieving SME status, we will benefit from a 90% fee reduction during the centralised procedure and GMP inspection fees of final product."

Regulatory Agency	**European Medicines Agency (EMEA)**
Sponsor	**CLINUVEL (UK) LIMITED**
INN NAME	Afamelanotide
Status SME	Small/autonomous enterprise
Validity	2 years
EMEA objective	To promote innovation and the development of new medicinal products
Commission Recommendation 2003/361/EC12 The EU incentives offered by Regulation (EC) No 2049/2005: • Regulatory, administrative and procedural assistance from the EMEA's SME Office; • Fee reductions for scientific advice, inspections and (for veterinary medicines) establishment of maximum residue limits; • Fee exemptions for certain administrative services of the EMEA; • Deferral of the fee payable for an application for marketing authorisation or related inspection; • Conditional fee exemption where scientific advice is followed and a marketing authorisation application is not successful; • Assistance with translations of the product information documents submitted in the application for marketing authorisation.	

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

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.

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