



Clinuvel communications

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- CEO Blog: *Broader implications of a landmark announcement;*
- *Patient driven drug development;*
- *Changing the rules in pharmaceutical development*

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Company Announcement

Monday 17th May 2010
Melbourne, Australia

Italian Medicines Agency (AIFA) provides reimbursement for the treatment of EPP with afamelanotide

Afamelanotide to be prescribed as medicinal photoprotectant to Italian patients

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that afamelanotide has been included in the list of drugs reimbursable by the Italian National Health System (Sistema Sanitario Nazionale, SSN) for the treatment of erythropoietic protoporphyria (EPP). Afamelanotide can now be prescribed as a photoprotective drug for Italian patients diagnosed with EPP under Law 648/96. Clinuvel will be fully reimbursed by the SSN for all units of afamelanotide prescribed.

In approving the listing the Italian Medicines Agency's (AIFA's) Technical and Scientific Committee (Commissione Consultiva Tecnico Scientifica, CTS) recognised the innovative value of afamelanotide in the treatment of EPP, a rare and severe disease for which no therapeutic alternatives exist.

Further to the Italian regulatory listing of afamelanotide, Clinuvel is preparing to file for approval of marketing authorisation in Europe through the centralised procedure of the European Medicines Agency (EMA), and will decide the timing of filing pending the final results of its Phase III European EPP trial (CUV017). Clinuvel's objectives are to file in the US through the FDA, subject to further data on safety and efficacy of the drug.

The 648/96 listing marks a significant event for Clinuvel from a medical, regulatory and commercial perspective as it has set a precedent in Europe.

About Law 648/96

Law 648/96 enables Italian patients to gain access to innovative treatments for disorders where no alternative therapy is available. The law applies to drugs already approved in other countries but not yet in Italy and to drugs which have demonstrated clear benefit while "under clinical investigation". A list of drugs approved for treatment under this law is published on AIFA's website, together with the approved indication. Previously, only 36 drugs had been included in the list since the law came into force in 1996. Afamelanotide is the first dermatology drug "under clinical investigation" to be awarded inclusion on the Italian list of reimbursable drugs.

A drug is considered for insertion in the 648/96 list following a request to CTS from physicians specialised in the treatment of the proposed disease, a University or a research centre. The request must be supported by a scientific dossier, which is reviewed by the CTS. The Scientific Committee may award the drug inclusion on the list for reimbursement, under exceptional circumstances and following compelling clinical results.

Through inclusion in the 648/96 list, afamelanotide can now be prescribed on an individual basis to adult patients diagnosed with EPP. Beneficiaries may be either former participants in clinical studies (CUV017) or other patients who are positively diagnosed with EPP.

Although the exact prevalence of EPP in Italy is unknown, it is estimated that approximately 60 patients will initially benefit from this treatment. Afamelanotide's inclusion on the 648/96 list has been formally announced by Italian legislators, allowing the drug to be prescribed to patients with immediate effect.

Afamelanotide and EPP

EPP is a rare metabolic disorder characterised by absolute intolerance to UV and visible light (blue spectrum), caused by the accumulation of protoporphyrin IX in the skin. EPP symptoms are reported as most severe during spring and summer months, when ambient UV levels are most intense. Afamelanotide was granted orphan drug designation (ODD) for EPP by the FDA's Office of Orphan Products Development, the EMA and Swissmedic in 2008.

Afamelanotide is in the late stages of clinical development for use in EPP. The first randomised placebo-controlled clinical trial (CUV017) has been completed in the Europe, Switzerland and Australia. Final data from this trial are being evaluated and results are expected in the near future. Initial clinical observations from the Italian cohort of CUV017 patients will be presented at the Sidemast Italian Dermatology Congress (Congresso Sidemast Dermatologia) in Rimini, Italy, on Friday May 21.

A confirmatory European Phase III trial (CUV029) and a US Phase II trial (CUV030) are under way. These studies are expected to confirm the safety and efficacy of afamelanotide in a larger population of EPP patients.

Clinuvel's Chief Scientific Officer, Dr Hank Agersborg said:

"A main objective of Clinuvel is to develop afamelanotide for patients for whom there is no other effective medical therapy and to provide the drug to these patients wherever possible. Italy's regulators have taken a leading complimentary position by acknowledging that porphyria is a disease requiring treatment and realising afamelanotide's potential to assist EPP patients.

"Although ultimate proof of effectiveness will be based on the results of further controlled clinical trials, support for the drug from the medical community is certainly very encouraging. Most importantly this is a clear win for Italian EPP patients, who have now gained access to a treatment which offers them the ability to lead a normal life."

Clinuvel's CEO, Dr Philippe Wolgen said:

"The listing and the award for reimbursement by AIFA were based on evaluation of the scientific evidence of afamelanotide's longer-term safety profile as well as its clinical benefit in EPP. Today's regulatory recognition and introduction of afamelanotide is remarkable and it supports our objective to provide dermal photoprotection to those patients who are most affected by the effects of ambient light and UV.

"For Clinuvel the news is an historical event in that the revenues will enable us to recover the costs of drug supply to Italian patients. For our shareholders this will be further proof that strategic choices to develop afamelanotide in orphan diseases, where the clinical need is high, are appropriate and justified in today's challenging pharmaceutical environment. "

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About afamelanotide

Afamelanotide is a first-in-line therapeutic being developed by Clinuvel. An analogue of α -MSH, afamelanotide is a linear peptide which activates the skin to produce eumelanin, the dark pigment which is known to have photoprotective properties (providing skin protection against light and UV radiation). Increased pigmentation of the skin appears a few days after administration of afamelanotide and lasts up to 60 days. 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. Pending positive clinical results, Clinuvel aims to file afamelanotide for its first market approval for the orphan indication porphyria (EPP).

Clinuvel is currently testing afamelanotide in five clinical indications:

Indication	Description	Clinical Trial Status
Erythropoietic Protoporphyrin (EPP)	Absolute sun/UV intolerance	Phase III trial full results due Confirmatory Phase III trial approved August 2009
Actinic Keratosis (AK) and Squamous Cell Carcinoma (SCC) in Organ Transplant Recipients (OTRs)	Skin cancer in transplant patients	Phase II trial started October 2007
Polymorphic Light Eruption (PLE / PMLE)	Severe sun/UV poisoning	Phase III trial preliminary results reported December 2009
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 reported December 2009*

*Program deferred February 2010.

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 Erythropoietic Protoporphyrin (EPP)

Porphyrias are a group of inherited disorders with enzymatic deficiency in the blood synthesis pathway (also called porphyrin pathway). They are broadly classified as erythropoietic porphyrias based on the site of the overproduction and main accumulation of porphyrin. They manifest with either skin problems, neurological complications or gastro-intestinal problems (occasionally all).

EPP is a rare genetic disease found in people with fair skin. It is characterised by severe phototoxicity (or intolerance to light) of the skin resulting in intolerable pain, swelling, and scarring, usually of the hands and face. The pain experienced and expressed by EPP patients when their skin is exposed to light is reported as intolerable. EPP patients are often forced to remain indoors, severely affecting their quality of life.

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Clinuvel is an Australian biopharmaceutical company focussed 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