SCENESSE® Commercialisation Update

SUMMARY
- SCENESSE® Risk Management Plan infrastructure nearing finalisation
- EPP expert centre training commences this week

Leatherhead, UK and Melbourne, Australia, June 5, 2015

Clinuvel Pharmaceuticals Ltd **(ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY)** today announced an update on the commercial distribution of its drug SCENESSE® (afamelanotide 16mg) for erythropoietic protoporphyria (EPP) across Europe. SCENESSE® was granted marketing authorisation by the European Commission for adults diagnosed with EPP on December 22, 2014.

A number of post-authorisation commitments were agreed with the European Medicines Agency (EMA) under a long-term risk management plan (RMP) for SCENESSE®. The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) is scheduled to complete the final review of commitments relating to the distribution of SCENESSE® in September 2015.

POST-AUTHORISATION COMMITMENTS
The RMP requires that patients receiving SCENESSE® are monitored for long-term safety. This includes the establishment of a Centralised European EPP Disease Registry and a post-authorisation safety study (PASS) of all patients receiving SCENESSE®. PRAC is currently finalising its review of the Disease Registry.

In accordance with relevant European legislation[1] the Disease Registry is set up allowing trained physicians to enter anonymised medical information on the real-time use of SCENESSE®. Clinuvel is responsible for providing biannual safety reports to the EMA for the first 24 months following product release. An independent Governance Board and Data and Safety Monitoring Board oversee the management of the Disease Registry.

EUROPEAN TRAINING OF EPP EXPERT PHYSICIANS
As part of its European regulatory commitments, Clinuvel is required to adequately train expert physicians and their professional staff prior to prescribing SCENESSE®.

The first European EPP Expert Convention takes place on June 5 in Paris. In total 33 physicians from 23 different centres across 15 countries are represented. This convention will instruct expert physicians and specialists on the use of the Disease Registry and the administration of SCENESSE®.

Clinuvel will host a number of these expert meetings concomitant with the European distribution of SCENESSE®.

DISTRIBUTION OF SCENESSE® IN ITALY AND SWITZERLAND
Special Access Schemes which started in 2010 allow the distribution of SCENESSE® in Italy and Switzerland. A recent publication reported on the longer term follow up of 115 EPP patients from these programs.[2]

COMMENTARY
"My team is putting all the required processes in place in accordance with the EMA's principles and we have progressed our distribution of SCENESSE®," Clinuvel's Acting Chief Scientific Officer, Dr Dennis Wright said. "The extent of the interest shown in prescribing SCENESSE® for EPP has exceeded our expectations for today's convention."

"It is a considerable undertaking to put in place the quality management systems and processes required by the EMA," Clinuvel's Director Clinical Affairs Dr Emilie Rodenburger said. "While EMA progress is taking longer than we wish for, our team is clearly excited by the approaching landmark of treating EPP patients."

"The past months have demonstrated clinical demand from EPP patients, especially from countries where Clinuvel had not been before," Dr Rodenburger said.

REFERENCES

[1] The European Convention on Human Rights, Article 8 of the Charter of Fundamental Rights of the European Union, and the Data Protection Directive 95/46/EC.

[2] Biolcati G, Marchesini E, Sorge F, Barbieri L, Schneider-Yin X and Minder E (2015). "Long-term observational study of afamelanotide in 115 patients with erythropoietic protoporphyria." *Brit J Dermatol*. 172(6):1601-12. E-pub Dec 13, 2014. Available online: http://onlinelibrary.wiley.com/doi/10.1111/bjd.13598/pdf.

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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 disorders. With its unique expertise in understanding the interaction of light and human skin, the company has identified patient populations with a clinical need for photoprotection and another population with a need for repigmentation. These patient groups range in size from 5,000 to 45 million. Clinuvel's lead compound, SCENESSE® (afamelanotide 16mg), a first-in-class drug targeting erythropoietic protoporphyria (EPP), has completed Phase II and III trials in the US and Europe, and has been approved by the European Commission for treating adults with EPP. Headquartered in Melbourne, Australia, Clinuvel has operations in Europe, the US and Singapore.

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