SCENESSE® treatment in Europe

German Porphyria Expert Centres to start distribution of SCENESSE® (afamelanotide 16mg)

Melbourne, Australia and Leatherhead, UK, May 18 2016

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced an update on the company's post-authorisation distribution of SCENESSE® (afamelanotide 16mg) across Europe for adult patients with the rare disorder erythropoietic protoporphyria (EPP).[1]

SCENESSE® in EPP

SCENESSE® is the first approved treatment for EPP, a genetic disorder characterised by acute phototoxic reactions (anaphylactoid reactions and burns) and forced withdrawal from exposure to all forms of visible light.

Clinuvel conducted clinical trials of SCENESSE® in EPP from 2006 to 2013. During this time the company evaluated the treatment in 352 EPP patients. After completion of the clinical trial program, approximately 130 patients across eight countries (Australia, Austria, France, Germany, Italy, Sweden, Switzerland and The Netherlands) received SCENESSE® free of charge. In total 601 implant injections were provided to patients free of charge under compassionate use schemes. The development program and the following compassionate use program was supported entirely by equity funding.

Subsidised access to SCENESSE® treatment, prior to the drug's formal commercial approval, was made possible in both Italy and Switzerland from 2010 and 2012 respectively. These two programs enabled 115 EPP patients to benefit from treatment with SCENESSE® totalling more than 200 patient years of cumulative care. Clinuvel is no longer in the position to provide access to SCENESSE® on a subsidised basis.

Regulatory and clinical obligations prior to SCENESSE® distribution

The European Medicines Agency (EMA) granted SCENESSE® marketing authorisation under a strict risk management plan, comprising a Post-Authorisation Safety Study (PASS) as well as a Retrospective Chart Review (RCR) to follow up those who do not consent to participate in the PASS. The process of regulatory drug release and approval of the pharmacovigilance systems required a further 18 months of in-depth discussion with the EMA. The EMA's pharmacovigilance subcommittee (PRAC) formally endorsed the last of these protocols on April 14, 2016. The final regulatory and clinical steps prior to the start of the treatment are a review of the PASS and RCR protocols by some of the local ethics committees and the approval of patient and physician educational materials by various National Competent Authorities.

SCENESSE® as High Specialty Care in Porphyria Expert Centres

SCENESSE® is only being made available to EPP patients through Porphyria Expert Centres, which require training and accreditation by Clinuvel.

In Germany it is anticipated that the first year three Porphyria Expert Centres – in Berlin, Chemnitz, and Düsseldorf – will be able to prescribe the treatment. The German national authorities have released their first assessment of the use of SCENESSE® in EPP. In parallel, 13 German insurance firms have agreed to make SCENESSE® available to EPP patients. It is the company's expectation for a uniform commercial price to be in place across Europe. Discussions are underway with authorities in nine countries to make SCENESSE® available, with further submissions anticipated in 2016.

Supporting rare diseases online

Recognising the disparate nature of information on rare diseases online, Clinuvel is launching a new website – *in beta version by May 31 and live by July 1* – focusing on the clinical aspects of EPP and research into the disease. The site will also serve to connect patients with Porphyria Expert Centres and diagnostic labs.

Commentary
"The long term success of SCENESSE® lies in the safety profile of the product for EPP patients and, hence, our and regulators' focus on pharmacovigilance," Clinuvel's chair, Mr Stan McLiesh said. "Now we look forward to the release of the photoprotective product by the various ethics committees to finally make the wishes of EPP patients a reality."

"After years of subsidising the treatment and providing it free of charge, Clinuvel needs to move towards the next stage of development: investing in a treatment for children with EPP. It has long been our desire to bring light to these children. Both decision makers and the medical community agree that Clinuvel should provide a pharmaceutical answer to EPP children," Mr McLiesh said.

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[1] SCENESSE® (afamelanotide 16mg) is approved in Europe as an orphan medicinal product for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with EPP. The innovative nature of the therapy in the orphan disorder, the lack of available scientific instruments to adequately measure the therapy, ethical considerations and the drug's positive safety profile were some of the factors which led to the European marketing authorisation of SCENESSE®. Information on the product can be found on Clinuvel's website at www.clinuvel.com.

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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 Clinuvel has identified patient populations with a clinical need for photoprotection and for repigmentation. The worldwide prevalence of these patient groups range from 5,000 to 45 million. Clinuvel's lead compound, SCENESSE® (afamelanotide 16mg), was approved by the European Commission in 2014 for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP).

Headquartered in Melbourne, Australia, Clinuvel has operations in Europe, Switzerland, the US and Singapore.
For more information go to http://www.clinuvel.com.

Forward-Looking Statements
This release to the Australian Securities Exchange and to press may contain forward-looking statements, including statements regarding future results, performance or achievements. These statements involve known and unknown risks, uncertainties and other factors which may cause Clinuvel's actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Some of the factors that could affect the forward-looking statements contained herein include: that the FDA may require additional studies beyond the studies planned for product candidates or may not provide regulatory clearances, including for SCENESSE®; that the FDA may not provide regulatory approval for any use of SCENESSE® or that the approval may be limited; that Clinuvel may never file an NDA for SCENESSE® regulatory approval in the US; that the Company may not be able to access adequate capital to advance its vitiligo programs; that the Company may not be able to retain its current pharmaceutical and biotechnology key personnel and knowhow for further development of its product candidates or may not reach favourable agreements with potential pricing and reimbursement agencies in Europe and the US.