Clinuvel accredits first European EPP expert centres

As part of the European distribution of SCENESSE® (afamelanotide 16mg) in specialist centres

Melbourne, Australia and Leatherhead, UK, March 15 2016

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that its European commercial team is conducting site training and accreditation at the first of the European expert porphyria centres this week. Following training these centres of expertise will be accredited to prescribe Clinuvel's drug SCENESSE® (afamelanotide 16mg) to adult patients diagnosed with erythropoietic protoporphyria (EPP).[1]

TREATMENT OF ERYTHROPOIETIC PROTOPORPHYRIA (EPP)

SCENESSE® has been approved by the European Medicines Agency (EMA) for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with EPP. The EMA has placed rigorous obligations on Clinuvel to monitor the long term safety of SCENESSE® in EPP patients who will be treated under a post-authorisation safety study (PASS).

"We have worked closely with a number of leading centres in anticipation of providing training and accreditation, and have fine-tuned how the EMA's requirements of safety reporting will work in practice," Clinuvel's Director, Clinical Affairs, Dr Emilie Rodenburger said. "In the coming weeks we expect patients to be contacted by accredited centres with an update on treatment availability."

"Pending confirmation of reimbursement from national healthcare systems and insurance providers for this specialised therapy, we can facilitate patient treatment in a number of European countries in the spring when patients are most at risk of anaphylactoid reactions triggered by an increasing light intensity," Dr Rodenburger said.

Clinuvel has implemented a structured training program for clinical staff in the multidisciplinary expert porphyria treatment centres throughout Europe. The company will ensure compliance with a treatment protocol as part of a PASS. Clinuvel will track and monitor pharmacovigilance, drug accountability, use of the European EEP Disease Registry (EEDR), and correct handling of the SCENESSE® drug product. Contracts with all expert centres aim to facilitate compliance with the PASS and continuous long-term care of EPP patients.

EUROPEAN REGULATIONS FOR PATIENT CARE

Risk management plans (RMPs) have become a regulatory norm in novel product distribution for companies to work collaboratively with global regulatory authorities in seeing through long-term product safety and effectiveness.

SCENESSE® is the first ever approved photoprotective therapy and, under its agreed RMP, will only be made available to EPP patients through accredited expert treatment centres. Patients treated under the PASS protocol can agree to the collection and scientific analyses of pseudonymised medical data stored in the EEDR.

- End -

[1] SCENESSE® (afamelanotide 16mg) is approved as an orphan medicinal product in Europe for the prevention of phototoxicity in adult patients with EPP. Information on the product can be found on Clinuvel's website at www.clinuvel.com.

Media enquiries

Lachlan Hay, Clinuvel (UK) Ltd.	+44 1372 860 765	Lachlan.Hay@clinuvel.com
Nick Miles, Cabinet Privé de Conseils s.a.	+41 22 321 4540	miles@cpc-pr.com
Ted Agne, The Communications Strategy Group Inc.	+1 718 631 3117	edagne@comstragroup.com

Investor enquiries

InvestorRelations@clinuvel.com

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 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.

Level 5, 160 Queen Street
Melbourne, Victoria 3000
Australia

T +61 3 9660 4900
F +61 3 9660 4999

www.clinuvel.com