Preliminary recommendation by NICE not to include SCENESSE® for reimbursement by NHS England

SCENESSE® subject to further review by NICE until May 2018

Leatherhead, UK and Melbourne, Australia 21 December 2017

CLINUVEL PHARMACEUTICALS LTD **[ASX: CUV; XETRA: UR9; NASDAQ INTERNATIONAL DESIGNATION: CLVLY]** today announced that the first draft assessment from England's National Institute for Health and Care Excellence (NICE) has been published, with SCENESSE® (afamelanotide 16mg) not recommended for reimbursement for the ultra-orphan disorder erythropoietic protoporphyria (EPP)[1], subject to NICE's final recommendation expected in May 2018. SCENESSE® is the only approved treatment for EPP patients in Europe and is currently under review as a highly specialised technology (HST) in England.

NICE reviews novel medical technologies and makes recommendations for their use by the English National Health Service (NHS). A final recommendation is expected to be made by the HST Committee in May 2018. The final recommendation by NICE - which if not appealed against by the company - may be upheld.

SCENESSE® has been authorised by the European Commission following a positive opinion by the European Medicines Agency. The drug is not currently reimbursed for EPP in England, notwithstanding that it has been adopted as standard of care for adult EPP patients in surrounding European reference countries. CLINUVEL has maintained a transparent uniform price for SCENESSE® applicable to all European countries (including Switzerland), the implementation of which would not exceed the NHS England budget threshold for new technologies.

"CLINUVEL is very disappointed with the preliminary assessment published by NICE, as it has not recommended SCENESSE® for EPP patients, who without SCENESSE® remain deprived of any effective treatment to their debilitating condition, and for whom no clinical care guideline exists in the UK," CLINUVEL's UK General Manager, Mr Lachlan Hay said. "However, the assessment process is still ongoing and NICE's preliminary assessment is only a first draft."

"We observe that NICE's publication did not include the critical budget impact test showing that the annual cost of SCENESSE® falls well within the budget threshold set by NHS England and NICE for novel technologies.

"Our teams are committed to making SCENESSE® available for all EPP patients in Europe and we will continue to work with authorities throughout Europe to seek access to SCENESSE® by EPP patients, who so badly need it," Mr Hay said.

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[1] SCENESSE® (afamelanotide 16mg) is approved in Europe as an orphan medicinal product 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.

About CLINUVEL PHARMACEUTICALS LIMITED
CLINUVEL PHARMACEUTICALS LTD (ASX: CUV; NASDAQ INTERNATIONAL DESIGNATION ADR: CLVLY; XETRA-DAX: UR9) is a global biopharmaceutical company focused on developing and delivering treatments for patients with a range of severe genetic and skin disorders. As pioneers in understanding the interaction of light and human biology, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for photoprotection and repigmentation. These patient groups range in size from 5,000 to 45 million worldwide. CLINUVEL's lead product, 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). More information on EPP can be found at http://www.epp.care.
Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Switzerland, the US and Singapore.
For more information go to http://www.clinuvel.com.

SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

Media enquiries
Lachlan Hay, CLINUVEL (UK) LTD. +44 1372 860 765 Lachlan.Hay@clinuvel.com

Investor enquiries
InvestorRelations@clinuvel.com

Forward-Looking Statements
This release contains forward-looking statements, which reflect the current beliefs and expectations of CLINUVEL's management. Statements may involve a number of known and unknown risks that could cause our future results, performance or achievements to differ significantly from those expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: our ability to develop and commercialise pharmaceutical products, including our ability to develop, manufacture, market and sell biopharmaceutical products; competition for our products, especially SCENESSE® (afamelanotide 16mg); our ability to achieve expected safety and efficacy results through our innovative R&D efforts; the effectiveness of our patents and other protections for innovative products, particularly in view of national and regional variations in patent laws; our potential exposure to product liability claims to the extent not covered by insurance; increased government scrutiny in either Australia, the U.S., Europe and Japan of our agreements with third parties and suppliers; our exposure to currency fluctuations and restrictions as well as credit risks; the effects of reforms in healthcare regulation and pharmaceutical pricing and reimbursement; any failures to comply with any government payment system (i.e. Medicare) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; any failure to retain or attract key personnel and managerial talent; the impact of broader change within the pharmaceutical industry and related industries; potential changes to tax liabilities or legislation; environmental risks; and other factors that have been discussed in our 2017 Annual Report. Forward-looking statements speak only as of the date on which they are made and the Company undertakes no obligation, outside of those required under applicable laws or relevant listing rules of the Australian Securities Exchange, to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. More information on the forecasts and estimates is available on request. Past performance is not an indicator of future performance.

Level 6, 15 Queen Street T +61 3 9660 4900 www.clinuvel.com
Melbourne, Victoria 3000 F +61 3 9660 4999
Australia