CLINUVEL reaches agreement on German SCENESSE® pricing through AMNOG Arbitration Board

Melbourne, Australia, and Leatherhead, UK, 12 April 2017

CLINUVEL PHARMACEUTICALS LTD **(ASX: CUV; XETRA-DAX: UR9; NASDAQ INTERNATIONAL DESIGNATION ADR: CLVLY)** today announced that it had reached agreement with the German National Association of Statutory Health Insurance Funds (GKV-Spitzenverband or GKV-SV) for the treatment of erythropoietic protoporphyria (EPP) patients with CLINUVEL's drug SCENESSE® (afamelanotide 16mg).

CLINUVEL had been in mandatory 'negotiation' with GKV-SV since August 2016. Under the German Pharmaceuticals Market Reorganisation Act (AMNOG) a pricing agreement was reached after an Arbitration Board was called. The outcome of the Arbitration Board is legally binding for all state insurers ('Krankenkassen') in Germany.[a]

EPP TREATMENT WITH SCENESSE®

SCENESSE® is a first-in-class therapy for the treatment of adults with EPP, a poorly characterised and an ultra-rare metabolic disorder which causes severe phototoxic and anaphylactoid reactions in patients. In Germany, the disease affects between 500 and 1,090 patients (based on disease prevalence).

Reports from clinical studies and during conditions of use over the last decade have indicated that EPP patients treated with SCENESSE® obtain an 'improved life' by:

(i) losing their prodromal reactions ('warning signals' triggered by accidental light exposure);
(ii) losing their anxiety for burns and anaphylactoid reactions;
(iii) being able to gradually expose their skin to light sources; and
(iv) participating in daily activities which had been impossible prior to treatment.

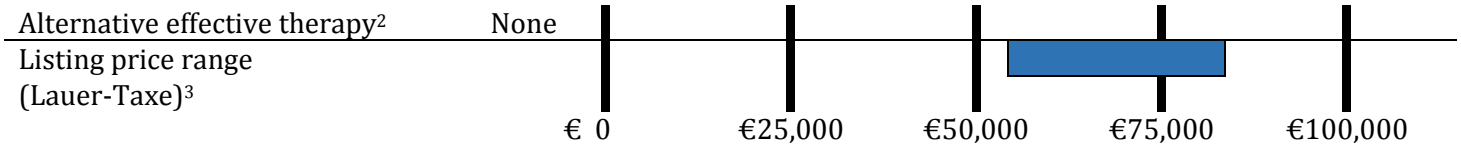
CLINUVEL monitors the ongoing use of SCENESSE® in EPP patients during its indefinite post-marketing authorisation program, which includes post authorisation safety study (PASS) protocols and a European EPP Disease Registry.

UNIFORM EUROPEAN PRICING

CLINUVEL has adopted a uniform global pricing policy and provides its clear rationale, acknowledging the facts that patients are migrating across borders to seek treatment, expert physicians are associated through porphyria networks, and hospitals collaborate internationally to purchase pharmaceutical products for orphan diseases. The company bears the risk of foreign exchange fluctuation over a period of 24 months (as of 15 February 2017) and will not make inflationary adjustments to the uniform price.

The annual costs of therapy with SCENESSE® range between €56,404 and €84,606 per EPP patient per annum. Figure 1. (below) highlights the main factors which were published by GKV-SV.

FIGURE 1: ANNUAL COSTS OF THERAPY IN GERMANY – SCENESSE® IN EPP[1]



[1]Price of treatment depends on number of implant injections per annum
[2]No alternative effective therapy exists for SCENESSE®
[3]Price in Lauer-Taxe is published by IFA GmbH

COMMENTARY

"The company is constrained as to the insight it can provide on the 'negotiations' and GKV-SV story," CLINUVEL's UK General Manager, Mr Lachlan Hay said. "It has been shown that SCENESSE® is priced uniformly in Europe, there is no alternative effective treatment for EPP, and as per EMA approval in 2014 there are no scientific instruments to quantify and measure the impact of disease or therapy.

"In an era where pharmaceutical companies are scrutinised by media, the general public, and insurers, we intend to set an example through our uniform product pricing policy. We run the company in an open and simple manner and therefore we will not engage in any incentivisation programme with any party. There is not an exception to this principle.

"This outcome is a well-deserved and long-awaited blessing for the German EPP patients and healthcare providers, who have been seeking clarity on pricing and supply conditions since the drug's European approval in October 2014. CLINUVEL commends the German Arbitration Board and its judges for its professionalism, independence and clear mind in its ruling. I thank my team who have worked very hard over a long time to arrive at this justified result," Mr Hay said.

- End -

Notes

[a] According to Sozialgesetzbuch Fünftes Buch (SGB V) section 130b, available online (German only) at https://www.gesetze-im-internet.de/sgb_5/.

About SCENESSE® (afamelanotide 16mg)

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 an 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

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 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). 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.

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 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 6, 15 Queen Street
Melbourne, Victoria 3000
Australia

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

www.clinuvel.com