Company Announcement

CLINUVEL COMPLETES SCENESSE® FDA FILING

Historic New Drug Application for the use of SCENESSE® *in rare metabolic disorder EPP*

EXECUTIVE SUMMARY

- First NDA for SCENESSE® (afamelanotide 16mg) in the United States
- First-line therapy proposed as systemic photoprotection for EPP patients
- Submission of data from five clinical trials in EPP, pooled data, Compassionate Use, Special Access Schemes, and real-world experience from European use
- Nearly 6,700 afamelanotide doses administered to more than 800 patients
- Priority Review requested to FDA

Melbourne, Australia, 25 June 2018

CLINUVEL PHARMACEUTICALS LTD **(ASX: CUV; XETRA-DAX: UR9; NASDAQ INTERNATIONAL DESIGNATION: CLVLY)** today announced that it has completed the submission of a New Drug Application (NDA) for its drug SCENESSE® (afamelanotide 16 mg) as the first proposed therapy for patients with the rare metabolic disorder erythropoietic protoporphyria (EPP) in the United States. An approved NDA will allow CLINUVEL to make SCENESSE® available to adult EPP patients in the US as a first-line therapy.

REGULATORY TIMELINES

Since 2005, CLINUVEL has been in regular and frequent communication with the US Food and Drug Administration (FDA) to discuss the development program for SCENESSE® as a preventative treatment for adult EPP patients.

The FDA granted SCENESSE® orphan drug designation for EPP in 2008. In July 2016 the FDA awarded Fast Track Designation allowing the Company to make its final regulatory submission.

Estimated FDA Timeline

22 June 2018	NDA Submission SCENESSE®
22 August 2018	Validation NDA
2019	Approval or Complete Response*

* Scientific review time depends on review status: Standard Review or Priority Review

On 24 October 2016, the FDA initiated a public Scientific Workshop on EPP in Silver Spring, Maryland, to gain more, and first-hand, information on the characteristics and impact of the disease from EPP patients and their families.

In November 2016, the FDA concluded that CLINUVEL's scientific data were ready to be filed as part of a rolling review for evaluation under an NDA. The rolling review enabled the Company to make its NDA submission in parts; the FDA's scientific review time starts once the final module has been filed and validated. The regulatory validation of the submitted dossier is now expected to take two months, after which a target date for the completion of the review may be provided (PDUFA date).

CLINUVEL has filed for Priority Review and awaits the FDA's answer to the request for scientific review on an abbreviated basis. Under a Priority Review, the FDA aims to arrive at a benefit versus risk assessment within six months from final submission, whereas a standard scientific review is estimated by the FDA to take up to ten months.

In October 2014 the European Medicines Agency (EMA) granted SCENESSE® marketing authorisation.[1] The product was launched in Europe in June 2016.

NDA DOSSIER FOR SCENESSE® IN THE TREATMENT OF EPP

As part of the NDA dossier, CLINUVEL submitted data and analyses from five clinical trials in EPP, data from Compassionate Use and Special Access Schemes, and data from the real-world experience of EPP patients receiving treatment in Europe. The data set consists of nearly 6,700 doses in more than 800 patients.

The safety profile of SCENESSE® has been positive to date and includes longer term exposure (over 12 years) from patients involved in multiple consecutive programs in Europe. A post-authorisation pharmacovigilance plan to monitor patients in the US long-term is part of the NDA submission.

COMMENTARY

"CLINUVEL has arrived at an historic moment," CLINUVEL's Chief Scientific Officer, Dr Dennis Wright said. "The scientific community started publishing on the use of melanocortins in man in 1987. It is owing to CLINUVEL's scientific team that new boundaries were broken to arrive at an innovative product providing systemic photoprotection in a genetic disorder for which there was no treatment. Today's NDA filing is the direct consequence of the many decisions our team has taken to persevere in the introduction of SCENESSE®, which facilitates a life for EPP patients that they had never known before. The time lapsed since first scientific concept not only illustrates the complexity of launching a novel molecule, but also shows the concentration of resources and passion necessary to realise this dream for patients worldwide."

"We consciously awaited validation of the EMA's Annual Report to add real world data to our FDA submission, since it is apparent that real-time data from patients demonstrate ultimately whether a novel pharmaceutical product offers the expected benefit or not. Since introducing SCENESSE® in Europe we have seen that over 98% of the EPP patients on treatment request the drug for a second treatment year. I specifically wanted to see the real clinical demand and, indirectly, effectiveness of the therapy, incorporated into our final NDA submission," Dr Wright said.

"In my capacity as Chair I have overseen the testing decisions our management team faced to implement a considered and well-thought out development program – one which I and many experts in the field view as one of the most remarkable turnarounds in pharmaceuticals in the Southern Hemisphere," CLINUVEL's Chair, Stan McLiesh said. "Vision, planning, diligence and patience was borne by our teams and led to today's NDA filing. I congratulate Dr Wolgen and Dr Wright, the CLINUVEL staff and management team for their persistence and delivery. We now keenly await the FDA's validation and review of the NDA submission."

– End –

[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 photomedicine and 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.

SCENESSE® is a registered trademark of CLINUVEL PHARMACEUTICALS LTD.

About erythropoietic protoporphyria (EPP)
Erythropoietic protoporphyria (EPP) is a rare metabolic disorder that causes severe anaphylactoid reactions to light (phototoxicity). Patients incur physical burns and ulcers, and are in a state of crisis following light exposure, summarised as phototoxicity. This usually occurs within minutes of exposure to bright lights, especially sunlight. EPP symptoms can be acute, or delayed (subacute), most often expressed as generalised oedema, effusion in tissue and distortion of the skin. As little as a few minutes of light outdoors (even when it is overcast or transmitted through a window) or artificial light exposure may be sufficient to evoke EPP symptoms. Phototoxicity is unresponsive to traditional pain and burn management techniques and patients can be incapacitated for days before reactions subside. Most patients withdraw from light exposure in order to manage their phototoxic symptoms.

Media enquiries

Europe: Lachlan Hay, CLINUVEL (UK) LTD. +44 1372 860 765 Lachlan.Hay@clinuvel.com
USA: Terri Clevenger, Continuum Health Communications, +1 (203) 227-0209, tclevenger@continuumhealthcom.com
Australia: Rudi Michelson, Monsoon Communications, +61 3 9620 3333, rudim@monsoon.com.au

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