



8 January 2014

Dear shareholders & friends of Clinuvel,

On behalf of the Clinuvel Board and our team I wish all of you a healthy and fortunate 2014. With much excitement our teams and all who are interested in Clinuvel are awaiting the outcome of the European Medicines Agency's (EMA's) review of SCENESSE® (afamelanotide 16mg implant) for erythropoietic protoporphyria (EPP) in this coming year. This process has taken longer than any of us could have anticipated, however we welcome the Agency's tenacity to ensure the drug is given proper evaluation and patients and physicians are given the opportunity to be heard.

The lengthy EMA review is perhaps indicative of the complexity of evaluating the first melanocortin as a viable therapy. We have frequently published how the choice was made to develop a therapy for EPP patients, and now we are at a stage where we can evaluate continuous treatment of adult EPP patients over seven years in Italy, Switzerland and other parts of Europe. Here I mention again that safety of a novel drug is a significant factor, most likely the dominant one during all regulatory evaluations in Europe and the US. As to juvenile EPP patients, it is our intention to finalise the development of a paediatric formulation when the EMA approval of SCENESSE® is confirmed. Work on this formulation commenced some time ago and it is the team's sincere wish to be able to offer a treatment to EPP patients under 18 when the impact of the disease is perhaps greatest.

As to the quality of the EMA review, our teams have expressed full confidence in the two rapporteurs coordinating on behalf of the Committee for Medicinal Products for Human Use (CHMP). As stated in Clinuvel's recent Annual General Meeting, the European regulatory evaluation will most likely involve interviews with patients, physicians and experts in porphyria, along with an invitation to our teams to present to the CHMP.

As to vitiligo, it has been apparent from the results in 2013 that the greatest need to treat is identified in patients of darker complexion (Fitzpatrick skin types IV-VI) where the disease is most visible, often very aggressive and has the greatest impact on patient quality of life. In line with these findings we are looking forward to starting the seven month trial in Singapore (CUV103), the first Asian trial conducted by Clinuvel.

In the National Skin Centre in Singapore we have consciously decided to engage with most experienced academic dermatologists and pigment cell experts in Asia. The preparation of this trial has taken close to one year, and the protocol design has involved input from global experts in vitiligo. While many treatments have focused on vitiligo, few have attempted the large scale evaluation of a therapy required to meet regulatory approval and we expect, once completed, Clinuvel's vitiligo program will be the largest of its kind for this pigmentary disorder. Because of this and other factors, we deemed it important from the start to ensure that international cooperation would take place between academic centres to provide consensus how to best treat these patients and how to structure a protocol to demonstrate a clinically significant treatment effect. We are presently awaiting ethics and regulatory approval to start the trial in Singapore.

Generally, the industry describes SCENESSE® as an innovative product in the fields of dermatology and metabolic disorders. While we pride ourselves to be innovators, we are also cognisant of the burden to be first in executing a novel concept in pharmaceuticals. We are fully aware of the potential of the family of

Australian Office	Level 14, 190 Queen St Melbourne Victoria 3000 Australia	T +61 3 9660 4900 F +61 3 9660 4999	US Office	40 Worth St, 10 th Floor New York, NY 10013 USA	T +1 646 527 7310 F +1 646 527 7309
European Office	Neuhofstrasse 3D, 6340 Baar Switzerland	T +41 41 767 4545 F +41 41 767 4546	Singaporean Office	9 Temasek Boulevard #29-01, 038989 Singapore	T: +65 315 751 34

www.clinuvel.com

melanocortins to be developed in other domains of medicine, however most important is to secure a first approval before starting new development programs. The abundance of literature and clinical work reveal the vast potential of melanocortins as therapeutics and diagnostics. In contrast, no company globally has managed to obtain formal marketing approval for a melanocortin thus far. Against this background I am confident that Clinuvel will be prima inter pares to achieve this long-awaited objective as experts and patients will always have the final say in the use of a novel therapy for unmet medical conditions.

My best wishes,



Philippe Wolgen,
Managing Director
Clinuvel Pharmaceuticals Ltd

Australian Office	Level 14, 190 Queen St Melbourne Victoria 3000 Australia	T +61 3 9660 4900 F +61 3 9660 4999	US Office	40 Worth St, 10 th Floor New York, NY 10013 USA	T +1 646 527 7310 F +1 646 527 7309
European Office	Neuhofstrasse 3D, 6340 Baar Switzerland	T +41 41 767 4545 F +41 41 767 4546	Singaporean Office	9 Temasek Boulevard #29-01, 038989 Singapore	T: +65 315 751 34