

3 November 2014

Dear Shareholders,

The EMA's approval of SCENESSE® (afamelanotide 16mg) on 23 October was an historic event for all stakeholders, most of all for the EPP patients who have been awaiting the therapy. The reactions from physicians and patients the past week have been overwhelming and emotive. Both groups expressed a sense of reprieve and state of euphoria; the long journey has had an impact on all. I am delighted that our teams have persisted and been able to make SCENESSE® available to all European EPP patients. I also readily admit that the conduct of the orchestra at times had been harder than ever anticipated, given the new domain of our technology. I often think about the people and families who all supported and remained in the five trials and who have been instrumental to the successful development.

We have witnessed that the positive effects of the EMA's approval have caused immediate ripples. Research groups have congratulated us as Clinuvel's regulatory achievement has now given additional credence to their own independent research on melanocortins. Some divisions have been working for three decades on MC-receptor binding, some on topics related to MITF expression and transcription factors to better understand the signaling and biology of the melanocyte, the primary target cell of SCENESSE®. In seeing a first in class product commercially approved, these scientific communities are indirectly receiving acknowledgement for the family of melanocortins currently being researched.

We forecast that the numerous interactions between Clinuvel and the EMA would lead to a convergence of knowledge for both actors. It eventually led to a novel approach in the context of drug development. Owing to the combination of the specific characteristics of erythropoietic protoporphyria (EPP; the tested indication) and impact of our novel drug we had opened a *sui generis* regulatory review. The communication between our teams and the European agency about rationale, need, relevance, and impact of treatment versus risk led to a lengthy process of information exchange. I laud Dr Wright's team and all staff who have overcome the many hurdles along the long way. Equally I must congratulate the EMA's executive management in London for the reform and progressive thinking about European drug development. The patient organisations in Europe and the US, and the porphyria specialists, deserve an ovation for their involvement.

In transitioning from a research to a commercial entity, clinical considerations and commercial value will be balanced. In the recent shareholder conference call I alluded to the fact that we are drastically restructuring Clinuvel to meet our growth requirements. One of our activities at present is to attract new skilled talent needed for the next chapter.

Expectations from all stakeholders are high, and our Board of Directors remains aware that we will always be balancing and trying to serve disparate interests.

At the Annual General Meeting on 28 November we will briefly review the European regulatory process and then look forward to the FDA's filing and expectations. We will also discuss the commercial roll out of SCENESSE® in Europe and the commercialisation processes being built for success.

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Now that Clinuvel has been able to meet the tallest of all challenges and has laid the foundation, our next and immediate focus is on realising enterprise value mid- and long-term.

After a decade of equity investments flowing from the selected institutional and professional investors the Board's and management's next task is to adjust its business plan. Years ahead of the EMA vote the Clinuvel Board and external advisors prepared for the two possible regulatory outcomes. With last week's outstanding result we now look at what is best for the Company, shareholders and, mostly, patients.

The Clinuvel Board wishes thank, on behalf of all patients, the financial sponsors who have provided direct financial support and shared the long term vision for SCENESSE® (listed in alphabetical order): The Agersborg family, Mr Alter, Mr Ashok, Baker Brothers, Mr Calvert-Jones, Cayros Capital, Diamond Network, Chartport, Cycladic Capital, the Ender Group, the European Investment Fund, Fidelity Investments, the Freedman Foundation, Mr James, the Jonen family, Mr Mitchell, Mr Najib, Mr Naphtali, the Otter family, the Riefler family, Mr Stanley, Mr Watkinson, the Wennmann family office, Mr Wilkie, the Wood family, and all those we have not yet been able to reach, wished to remain anonymous, or who we inadvertently may not have listed.

Yours respectfully,



Philippe Wolgen,
Managing Director
Clinuvel Pharmaceuticals Ltd

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