Clinuvel

COMMUNIQUÉ

February 2009

Overview from CEO

Welcome to a special edition of the Clinuvel Communiqué, reviewing two significant events in January 2009.

The **FDA IND** status, announced late January concludes an intense period of 16 months, during which time the entire Clinuvel team has compiled the FDA dossier. This file contains data generated and analysed over a decade. At a time when new drugs are being scrutinized by regulatory agencies worldwide, this IND is a remarkable achievement by our team. I congratulate all staff for their relentless pursuit to bring afamelanotide to market.

Our clinical program will commence in the US shortly with a pharmacokinetic study, which we anticipate will be followed by studies focusing on our clinical indications of PDT and EPP.

We are aware that the IND status will further increase Clinuvel's visibility in the US and beyond.

Last month, we were also able to publish the **first results from the Phase III study in erythropoietic protoporphyria (EPP)**. Whilst these initial data on 14 patients offered a positive indication of drug efficacy, we remain focused on monitoring the trials in Australia and Europe during 2009. In Q4, we expect to conclude the full study on 101 patients.

So far, it has been gratifying to learn from physicians and these data that severely affected patients benefit from afamelanotide.

Despite the good news, I emphasize that pharmaceutical development remains a risky endeavour where – at all times – two parameters ultimately determine the value of a clinical program: **safety and efficacy**.

Those who support and invest in Clinuvel must remain aware that pharmaceutical development is subject to the variables of biology; the unpredictability of drug and human response.

With my **urge for caution**, we are yet delighted that our choice to treat smaller severely affected populations with afamelanotide has yielded its first results.

In light of our clinical and regulatory progress, it is apparent that Clinuvel is attracting broader media interest. I refer to our media coverage on **clinuvel.com** to find latest print, online and TV coverage on the company.

Commensurate with Clinuvel's progress, we have witnessed inline with the business evolution of our company how some laboratories worldwide are now synthesizing illegal and untested chemical substances for online sale to the general public, often utilizing Clinuvel's pharmaceutical progress to justify the sale of these untested substances.

From analyses, Clinuvel has learned that none of the illegal chemical substances and formulations resembles the structure or composition of Clinuvel's afamelanotide.

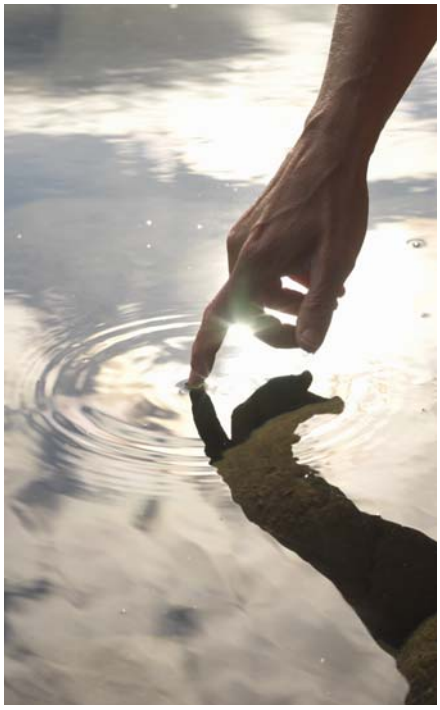
Clinuvel warns the general public against the use and self-administration of counterfeit products offered online, and urges the public to refrain from purchasing impure and untested substances. These illegal products pose a hazard to public health and may cause unknown long-lasting side effects.

Clinuvel supports the warnings issued by global regulatory agencies to curtail the online sale of illegal and untested chemical substances.

Finally, I congratulate the entire team in Europe, the US and Australia on its achievements. By continuing to commit to bringing afamelanotide to market, we hope to see further success in our development during the coming months.

Philippe Wolgen, MBA, MD

CEO



Company Background

Clinuvel Pharmaceuticals Limited is an Australian biopharmaceutical company developing its photoprotective drug afamelanotide for the treatment of UV-related skin disorders. Clinuvel's pioneering work aims to assist in preventing the global problem of UV-related skin disorders, by developing afamelanotide in areas of the greatest clinical demand.

Near Term Value Drivers (1H 09)

- Phase III interim results (PLE)
- Phase II full results (PDT)
- Commence US trials
- Trade name for afamelanotide

Erythropoietic Protoporphyria (EPP) Phase III interim results

Clinuvel has achieved positive interim results from its Phase III EPP study of treatment with its photoprotective drug afamelanotide. The 14 patients from a clinic in Zürich concluded 12 months treatment, alternating between active drug and placebo implant administered every 2 months.

The interim analysis found that the maximum severity of phototoxic reactions was significantly reduced by afamelanotide treatment compared to placebo ($p<0.001$) and the total severity of phototoxic reactions was reduced during spring and summer months by afamelanotide compared to placebo ($p=0.028$).

Skin melanin density increased following afamelanotide treatment and then declined during the placebo treatment period as expected. There was a significant difference in the change from baseline in melanin density (skin darkening) for afamelanotide compared to placebo for the first two treatment periods, during spring and summer ($p=0.048$).

All 14 patients requested continuation of treatment with afamelanotide for photoprotection for the next 12 months under compassionate use applications. These applications have been granted by SwissMedic, the Swiss regulatory agency.

Importantly, there were no afamelanotide-related serious adverse events or safety concerns identified during the study.

A further 87 patients will undergo treatment under the trial with full results anticipated before the end of 2009.

Potentially, afamelanotide could offer EPP patients the possibility of an existence where exposure to light and UV becomes tolerable, and where patients are not confined to life indoors.

Media Coverage

Leading US biotech industry journal *BioCentury* featured Clinuvel in a one page article in its 9 February 2009 edition.

Press coverage of Clinuvel's Phase III EPP results and IND included:

- TV coverage on *Today Tonight* (Australia) and *3News* (New Zealand);
- write ups in *The Australian*, the *Herald Sun, The Age* and *The Australian Financial Review* newspapers;
- online coverage at *Wired.com*, *Australian Life Scientist*, *BioShares*, *BioTechnologyNews.net, Biotech Daily* and *BioSpectrum Asia*.

Full media coverage can be found at clinuvel.com.

Meetings & Events

Clinuvel presented at the recent Sachs European Life Science CEO Forum in Zürich, February 2009.

The 67th Annual Meeting of the American Academy of Dermatology will be held in San Francisco in March 2009. A presentation will be given on the treatment of congenital erythropoietic porphyria (CEP) with afamelanotide.

Further meetings are scheduled and will be posted at www.clinuvel.com.

Published Research

Results from Clinuvel's Phase II EPP study (CUV010) were recently published in the *New England Journal of Medicine,* outlining the study of five EPP patients from a Zurich clinic who underwent treatment with afamelanotide. This study's encouraging results formed the basis for the current Phase III EPP trial.

For more information see:
Harms, J et al (2009).
"An α-Melanocyte-Stimulating Hormone Analogue in Erythropoietic Protoporphyria."
NEJM. 360(3): 306-307.
A copy of this article is available for viewing at Clinuvel's Melbourne office.

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