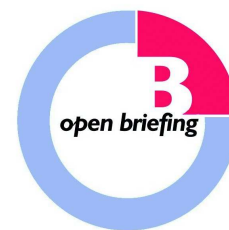


**Attention ASX Company Announcements Platform  
Lodgement of Open Briefing®**



**corporatefile.com.au**

Clinuvel Pharmaceuticals Limited  
Level 11  
330 Collins Street  
Melbourne, VIC 3000

---

**Date of lodgement:** 25-Aug-2009

**Title:** Open Briefing®. Clinuvel. CEO on Afamelanotide Commercialisation

**Record of interview:**

**corporatefile.com.au**

Clinuvel Pharmaceuticals Limited (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) provided an update on the commercialisation pathway for afamelanotide. You indicated that you're focussing on regulatory approval for two indications – Erythropoietic Protoporphyrria (EPP) and Solar Urticaria (SU). What was the rationale for focussing on these two indications?

**CEO Philippe Wolgen**

The mantra for drug developers ought to be that the clinic will show you where to go and for which therapeutic classes to develop a new drug. In all our assessments of the viability of commercial success, we looked at the most acute disorders for which an effective treatment is lacking. First of all, we believed that the motive of doing good for patients would result in clinical success, and armed with this belief we now stand a reasonable chance to develop afamelanotide as novel drug to market. Safety remains a prerequisite in our ongoing development. The above summarises our considerations for registering afamelanotide.

Importantly, drugs need to be assessed on chemistry, dose and formulation. These three factors need to go in parallel with some of the commercial choices.

We found EPP and SU to be the most acute indications following light or UV exposure to skin. An effective prophylactic drug would be of major clinical benefit to sufferers of EPP and SU. This therapeutic is currently missing in the clinic, and we seem to have found a feasible place for our drug. We're part of a select group of companies which has two orphan drug indications for one drug.

Both EPP and SU are orphan diseases with EPP receiving orphan drug designation (ODD) in Europe, Switzerland and US; and most recently SU was also granted ODD in Europe by the European Medicines Agency (EMA). The results and clinical feedback in combination with the lack of current therapies have led us to make EPP and SU our first priority towards regulatory approval.

**corporatefile.com.au**

What is the trial and approval timeline for the Phase III EPP trials in Europe?

**CEO Philippe Wolgen**

We defined ambitious goals four years ago to complete the current Phase III trials by the end of this calendar year. This is not the usual time span in our industry, it normally takes another three to four years longer. When we collectively meet this objective, we will have set a record breaking time in identifying one or more novel indications, confirming the clinical proof of concept, obtaining regulatory support worldwide and gaining the clinical support from all physicians and academics in the field. The completion of the European Phase III in EPP will sum up the team's achievements during the past four years.

We will inform the market on the progress of the trial by analysing (as laid out per protocol) the four-months European results in the third quarter of this calendar year. The results will follow once the independent data management and analyses are completed and confirmed by the Independent Data Safety Monitoring Board. The next steps will be to write and assemble a dossier to file for marketing authorisation application (MAA) with the EMA. Following our submission, timeframes will then be determined by the EMA.

**corporatefile.com.au**

The US Federal Drug Administration (FDA) has allowed afamelanotide to proceed with clinical trials in the US under Investigational New Drug (IND). You previously noted that you will commence US trials comprising of a pharmacokinetic (PK) and pharmacodynamic (PD) trial using the final commercial product as a controlled release formulation. Are you on track with these trials?

**CEO Philippe Wolgen**

These confirmatory trials will most likely finish by December. The US program is more or less linked with our EU direction. Most people who follow Clinuvel's development closely understand how seasonal influence uniquely plays an important part in our clinical program. We are obliged to carefully select and plan for the seasons (spring and summer) when we wish to conduct our trials; this is unique to afamelanotide. Looking ahead, we plan to expand our US activities early 2010 to match the full program in the EU.

**corporatefile.com.au**

Afamelanotide was granted ODD by the EMA in June 2009 for SU. Phase II results showed that the tolerance of the skin to light of various wavelengths and intensities was increased in SU patients after the administration of afamelanotide. What is the meaning of these results, and what are the next steps for Clinuvel?

**CEO Philippe Wolgen**

The clinical shift in application of afamelanotide is meaningful and unexpected, but then again this is part of discovering new fields. Results from the Phase II SU study indicate that afamelanotide is effective in providing photoprotection against light that ranges in wavelength from 300nm to 600nm. That is, the drug can mitigate the effects of light or UV in the skin as well as in the visible range causing acute skin disorders. The other key learning is that we are now able to pharmacologically control acute skin outbreaks, whereas chronic conditions require a different approach. We have come to assign numerical protection to our drug, and this will allow us to be more precise at picomolar concentrations during the registration of afamelanotide.

With this knowledge, we intend to progress SU to Phase III trials, which are being prepared for March 2010 in Europe. This trial will be of 6-months duration and will focus on ‘conditions of use’.

**corporatefile.com.au**

Afamelanotide is a novel drug. Given EPP and SU both have ODD status, what is your strategy on pricing the product?

**CEO Philippe Wolgen**

Pricing strategy is pivotal to the understanding of the markets and possibilities for reimbursement of the drug. A pricing study is underway in Europe to explore the range of pricing in ODD and improving the quality of life in patients that are house-bound. We hope to have these results by November this year.

**corporatefile.com.au**

How is Clinuvel going to manufacture afamelanotide on a larger scale? What is the manufacturing strategy?

**CEO Philippe Wolgen**

We will inform the market of our plans to manufacture on large scale shortly, and this will be part of our commercial direction.

**corporatefile.com.au**

Have you advanced partnering discussions regarding distribution?

**CEO Philippe Wolgen**

Like any company in our sector in Phase III stage, we’re exploring a number of options. Once this process is finalised we will discuss it, but not before.

**corporatefile.com.au**

What is the progress of your other three indications - Polymorphic Light Eruption (PLE), Photodynamic Therapy (PDT) and Actinic Keratosis (AK)?

**CEO Philippe Wolgen**

To date, our path to market has been dictated by the medical need. As I noted previously, our first priority is to develop afamelanotide for the two acute orphan indications EPP and SU. PDT is another acute indication which is in Phase II trials. We expect results from this trial before the end of this year.

EMEA has also granted ODD for the subacute indication Congenital Erythropoietic Porphyria (CEP). We're currently studying and collecting data for CEP under compassionate use. CEP is an ultra-rare but very severe disease; we will look at the clinical response in the Q1 2010.

The other two indications polymorphic light eruption (PLE) and actinic keratosis (AK/SCC) are chronic conditions, and the evaluation of our preventative drug will take longer. Currently, we're conducting a Phase III trial in PLE and expect to announce the interim results by the end of this year.

**corporatefile.com.au**

Cash reserves at the end of June 2009 were \$37.5 million. Do you have sufficient funding to complete the Phase III trials of EPP in Europe and US and apply for regulatory approval for afamelanotide? Is it necessary to raise capital in the short-term?

**CEO Philippe Wolgen**

We have ample cash available to complete this program and are fully funded for the filing for marketing authorisation for afamelanotide.

**corporatefile.com.au**

Thank you Philippe.

---

For more information about Clinuvel Pharmaceuticals Limited, view [www.clinuvel.com](http://www.clinuvel.com) or contact Head of Global Network and Communications, Lachlan Hay on +61 3 9660 4900 or via [investorrelations@clinuvel.com](mailto:investorrelations@clinuvel.com) or on Twitter @ClinuvelNews

For previous Open Briefings by Clinuvel Pharmaceuticals Limited, or to receive future Open Briefings by e-mail, please visit [www.corporatefile.com.au](http://www.corporatefile.com.au)

**DISCLAIMER:** Corporate File Pty Ltd has taken reasonable care in publishing the information contained in this Open Briefing®. It is information given in a summary form and does not purport to be complete. The information contained is not intended to be used as the basis for making any investment decision and you are solely responsible for any use you choose to make of the information. We strongly advise that you seek independent professional advice before making any investment decisions. Corporate File Pty Ltd is not responsible for any consequences of the use you make of the information, including any loss or damage you or a third party might suffer as a result of that use.