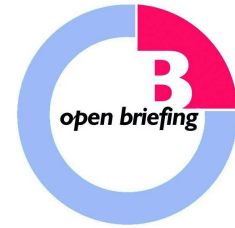


**Attention ASX Company Announcements Platform
Lodgement of Open Briefing®**



corporatefile.com.au

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

Date of lodgement: 29-Jan-2009

Title: Open Briefing®. Clinuvel. FDA Grants IND Status

Record of interview:

corporatefile.com.au

Clinuvel Pharmaceuticals Limited (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) today announced that the US Food and Drug Administration (FDA) has granted afamelanotide its Investigational New Drug (IND) status. What are the clinical and commercial implications of IND status?

CEO Philippe Wolgen

IND status is a meaningful acknowledgement that afamelanotide is a drug worthy of further investigation in the US, and we will now commence trials there. The IND process is extremely rigorous. In order for us to have received this status, all of the data we have collected relating to the technical quality, safety and efficacy in the pharmaceutical development of afamelanotide have been comprehensively reviewed by the US FDA. This result summarise 16 months of intense work in the company.

The commercial implications of the IND are various. It means we are now active in four separate jurisdictions (US, Australia, European Union and Switzerland) and have a clear gateway into the US market. This status will also increase the visibility of Clinuvel as a legitimate and credible player in the pharmaceutical and biotechnology industry and it may open up further opportunities, such as partnering and possible distribution. In short, it increases our overall chance of success.

corporatefile.com.au

What does IND status mean for the timing of possible commercialisation of afamelanotide?

CEO Philippe Wolgen

Our clinical program is most advanced in Europe where we are conducting Phase III clinical trials in the orphan indication erythropoietic protoporphyria (EPP) and intend to file for registration in the next 12 months. A US filing is likely to follow shortly thereafter for photodynamic therapy (PDT) and EPP. Marketing authorisation is typically granted within 9 to 12 months after filing in both jurisdictions.

corporatefile.com.au

Why are trials in the US so important to the company?

CEO Philippe Wolgen

The US pharmaceutical market represents 50 percent of the global pharmaceutical market. It's the largest developed country, and by far the largest pharmaceutical market in the world. IND status and successful trials in the US is a preferable route to enter this market. Obviously, entering the US has significant implications for Clinuvel's future and as such the trials there are very important to the company.

corporatefile.com.au

Clinuvel's first US trials will consist of a pharmacokinetic (PK) and pharmacodynamic (PD) trial using the final commercial product as a controlled release formulation. Can you comment on the difference between these trials and the other PK/PD trials you conducted in Europe and Australia?

CEO Philippe Wolgen

The confirmatory trial we are undertaking in the US is essentially the same in design as previous PK/PD studies we undertook in Europe and Australia. It is, however, important to confirm the product performance using the final manufacturing process proposed for the commercial product; this can be regarded as a bridging study to the PDT and EPP trials in the US.

corporatefile.com.au

EPP was granted orphan designation by the FDA in July 2008 and is near completion of the Phase III trials in Europe. You indicated that PK trials in the US will be followed by Phase II trials in PDT. What is the rationale behind conducting the Phase II trials in PDT first instead of the more advanced EPP?

CEO Philippe Wolgen

Various reasons underlie our decision to conduct trials on PDT in the US before EPP. Firstly, we wish to apply for an end-of-phase II meeting with the FDA before starting the EPP Phase III trials in the US. This interface will offer the FDA to have a valuable input in this pivotal trial. Secondly, there is biochemical commonality between PDT and EPP and we wish to demonstrate the reduction of phototoxicity in both indications following oncology treatment.

For EPP, we aim to demonstrate the reduction in the severity of phototoxicity in sufferers of the disorder. The molecular mechanism in both indications is quite similar, meaning that the pain experienced by these patients is elicited by the same family of molecules in the skin. We believe that those two indications will be the first for which we will register the drug in the US.

corporatefile.com.au

Cash and short-term investments as at the end of September 2008 was \$47 million. Given the commencement of trials in the US what will be your total cash spend in calendar 2009?

CEO Philippe Wolgen

Our projections remain the same. Cash burn should be in the region of \$17 million for calendar year 2009, and this number includes our activities in the US.

corporatefile.com.au

What is your current strategy in relation to the commercialisation of afamelanotide? Do you have any intentions to take on partners?

CEO Philippe Wolgen

We do not exclude the possibility of entering into partnerships. It was always our belief that once we obtained interim results for Phase III trials and an IND, we would be in a stronger position to assess the viability of a collaboration with a larger pharmaceutical company. Having reached those milestones, we can now explore that possibility.

corporatefile.com.au

What plans do you have to manufacture commercial quantities of afamelanotide?

CEO Philippe Wolgen

The process of planning and scaling up the manufacture of afamelanotide is a lengthy process and there is a good deal of work to be done in terms of projecting demand for the drug. We continue to work closely with our manufacturers to ensure that we will be able to meet demand for the drug if and when we go to market.

corporatefile.com.au

What options do you have for distributing the drug?

CEO Philippe Wolgen

We have several options. We could distribute the drug ourselves, we could source distribution partners in individual regions or we could appoint a single, global distributor. Companies with a strong track record in drug development do not necessarily have strong capability in drug marketing and distribution. As such, we are examining the options available to us, and will go with the one that we believe will be most advantageous to Clinuvel when it's appropriate. As I said before, we do not exclude the possibility of entering into partnerships.

corporatefile.com.au

What material milestones are you aiming to achieve throughout 2009?

CEO Philippe Wolgen

Getting Clinuvel's trials in the US underway will be a major milestone for us in 2009. We will also finalise the first data from the trials of afamelanotide administered to patients undergoing photodynamic therapy (PDT), or suffering from solar urticaria (SU) or polymorphous light eruption (PLE).

Afamelanotide will be branded and given a trade name, and we will begin to undertake further recruitment of staff to enhance the pool of talent within the company. 2009 will be a significant year in the Clinuvel story and we've very pleased to have reached this point. As a final remark, I firmly believe in that the first rule of Hippocrates still holds in this industry: first do good; the rest will follow.

CEO Philippe Wolgen

Thank you Philippe.

For more information about Clinuvel Pharmaceuticals Limited, view www.clinuvel.com or contact Head of Corporate Development Colin Mackie on +61 3 9660 4900 or via investorrelations@clinuvel.com

For previous Open Briefings by Clinuvel Pharmaceuticals Limited, or to receive future Open Briefings by e-mail, please visit 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.