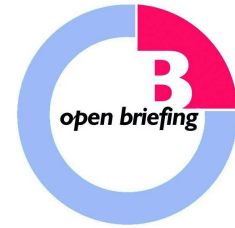


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Level 11
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Title: Open Briefing®. Clinuvel. Submission of IND Application

Record of interview:

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Clinuvel Pharmaceuticals Limited (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) today announced it has submitted an Investigational New Drug (IND) application to the US Food and Drug Administration (FDA) to conduct trials of its photoprotective drug, afamelanotide (CUV1647). What key information or data emerged in the IND application?

CSO Hank Agersborg

An IND if approved by the FDA will allow a compound to be tested in clinical trials in the US. Unlike in Europe and Australia where summaries are permissible, in the US we need to submit not only the summary of the previous experience, but also full documentation and final reports of all previous preclinical or clinical activity. Three areas of information are required in the application - chemistry, manufacturing and controls (CMC), animal study data including pharmacology and toxicology and protocols for proposed clinical trials and investigator information. Following the IND approval, the plan is to investigate Photodynamic Therapy (PDT) and Erythropoietic Protoporphyrin (EPP) in the US.

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Typically, what is the focus of the FDA when assessing the merits of an IND filing?

CSO Hank Agersborg

The FDA is in the business of assessing safety and efficacy. That's the focus. They'll assess the CMC information we submitted to ensure that we can produce and supply consistent batches of the drug. The animal safety data

enables them to evaluate whether afamelanotide may be administered to humans with minimal risk, while the protocols for the proposed trials allow the FDA to assess whether the trials will expose patients to any unnecessary risks. So, to get an IND, we have to demonstrate potential safety and efficacy for afamelanotide.

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To what extent is this IND application a stepping stone to Clinuvel's ultimate success towards commercialisation?

CSO Hank Agersborg

The US is the biggest pharmaceutical market in the world and to enter this market is a major milestone. Once an IND application is approved, it allows us to conduct clinical trials. Upon success of the trials, we will submit a New Drug Application (NDA) to allow us to market afamelanotide in the US.

The IND application will also be of value in cases where we wish to interest other companies in our expertise and product. However, we do want IND approval prior to discussing arrangements with any other company.

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When do you think it's realistic that afamelanotide will be a commercialised drug?

CSO Hank Agersborg

I hope that by late 2009 we would have data to submit to regulatory agencies in Europe. The US submission would obviously follow later. We would use data collected from the US in conjunction with the European data for submission in Europe.

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Why have you chosen PDT as a key indication in the US?

CSO Hank Agersborg

PDT is a trial in which a single dose can demonstrate efficacy. The other indications may involve up to twelve doses two months apart over one to two years. In this instance, the efficacy can be assessed very quickly. Afamelanotide increases melanin in the skin and overcomes problems associated with phototoxicity. Our intention is to give an adequate quality of life to a cancer patient who may still have limited survival after treatment.

PDT is currently in Phase II in five centres in Europe, and we'll initiate Phase II studies in the US. We will be conducting trials on PDT initially and then on Erythropoietic Protoporphyrin (EPP). EPP is a disease of relative small number of patients, but requires a minimum of one year treatment to demonstrate efficacy throughout all seasons.

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The US FDA, European Medicines Agency (EMA) and Swissmedic recently granted Orphan Drug Designation for EPP in afamelanotide. Do these designations have any weighting on the FDA's decision on the IND application?

CSO Hank Agersborg

A drug is designated an orphan if fewer than 200,000 people in the US have the disease. Orphan designation may be useful for an IND application although we still have to submit an IND and go through the review process but there's usually leeway allowed in the protocols. For example, it may be difficult to reach the number of patients required to test for efficacy, so instead of requiring for example 200 patients, 50 patients or less might be sufficient.

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Cash and short-term investments as at the end of September 2008 was \$47 million. What is your funding strategy for the trials if the IND application is approved?

CSO Hank Agersborg

We retained cash and short-term instruments equal to \$47 million and remain in a solid position to conduct trials moving forward. We expect cash burn rate to increase from \$1 million to \$1.7 million in late 2009 considering the increased operational activities. However, we have enough cash to fund at least the first part of clinical studies in the US.

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Finally, can you outline the potential milestones you expect to achieve in the next 12 months?

CSO Hank Agersborg

We've now submitted the IND and are hopeful it will be approved, which is a prominent milestone. During 2009, we also expect trial results in the US in PDT.

Other milestones outside the US will be a continuation of our clinical work. In the next 12 months, we will receive interim results from the Phase III EPP and PLE trials. Completion of the Phase III EPP trials are foreseen by Q4 2009. By this time next year we will have collected several hundred patients on the other indications as well. We are also excited to initiate trials for EPP in paediatrics next year and looking forward to adopting a trade name for afamelanotide. All these will help us to be one step closer to a marketing authorisation.

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Thank you Dr Agersborg.

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

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