Clinuvel Communiqué
February 2010

CEO's Outlook For 2010

Final Development In Erythropoietic Protoporphyria (EPP)

The year 2010 is a pivotal one, in which the Clinuvel team intends to file (pending positive and ongoing human safety) the first registration dossier for afamelanotide. All aspects of the registration will be monitored by Dr Agersborg, Dr Wright and our extensive team worldwide.

Exactly four years ago current management obtained the mandate to develop afamelanotide for clinical use in the most severe light and UV related skin disorders. In this evaluation, EPP was identified as a most severe disorder affecting adult and juvenile patients (and their parents). In time we have given EPP the priority it deserves in the overall program.

In various publications, we have stressed our objective to commercially develop afamelanotide as the first melanocortin on the market. The scientific attention paid to melanocortins or alpha-MSH may well be a hint for the clinical demand worldwide. A recent search on Pubmed (the global reference for scientific publications) gives 4,212 articles on alpha-MSH, 10,361 on skin pigmentation, 1,777 on melanogenesis and 532 publications on melanocortin 1 receptor (MC1R). Taking on board the frequent feedback Clinuvel continuously receives at basic science as well as advanced clinical level, we are fully aware that afamelanotide serves as a complementary tridecapeptide in patients who are most deficient in their physiological skin response to UV damage.

In designing a pharmaceutical development program, one easily and often assumes that physicians are

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Events Where Clinuvel Is Represented

Recent:

- Gastro 2009 – London (November)
- WCPD 2009 Pediatric Dermatology Congress – Bangkok (November)
- JP Morgan 28th Annual Healthcare Conference – San Francisco (January)
- Swiss Society for Porphyria Annual General Meeting – Zurich (January)

Upcoming:

- Sachs Associates 3rd Annual European Life Science CEO Forum – Zurich (February)
- Annual Scientific and Clinical Excellence Meeting – Luzern, Switzerland (20-21 February)
- BIO Europe Spring 2010 – Barcelona (March)

willing to administer their patients newly developed therapies. Equally, in the planning stages one tends to readily project that patients with rare diseases (orphan disorders) are willing to travel long distances to expose themselves to a new experimental pharmaceutical therapy. Frequently these assumptions are unrealistic. Recruitment and retention is often a major issue in the failure to attract sufficient patients. Lack of interest frequently signals the end of a pharmaceutical program, even at advanced stages. Therefore, learning from the orphan programs around us, we have paid much attention to the recruitment and retention of patients in our trials and heeded to the clinical feedback we obtained. In our EPP trials – testing a rare disorder – we have maximised the participation of physicians and patients worldwide; a clinical success in the industry.

In our program the Clinuvel team stays close to the pharmacological principle of a new drug development by closely respecting the ligand specificity of MC1R. In lay terms it means that the specific cell receptor on the melanocyte (pigment producing cell) responds optimally to our drug, due to the formulation and concentration we have purposefully developed. Afamelanotide acts as a local (paracrine) hormone on the epidermal cells to support the activation and release of cellular pigment prior to UV and light damage.

In afamelanotide 16mg controlled-release formulation, we have developed a selective agonist of the melanocortin 1 receptor. With the objective of providing medicinal photoprotection, we possess a world's first and have identified the best use for the drug in EPP patients. They are unable to lead a normal life and hide from ambient light; these patients are often misunderstood and are unable to express the clinical ordeal of literally 'burning' to light upon the slightest skin exposure. In contrast, most of these patients had accepted that no treatment would be available for them.

To all involved in Clinuvel, I stress that it is a privilege in pharmaceuticals to receive clinical reports from both physicians and patients who attest during and after the clinical trials that afamelanotide facilitates outdoor exposure and activities which were previously impossible. The ability to provide a treatment for these adult patients is meaningful, and we anticipate that Clinuvel will also be able to provide treatment for children in the near future. Two sets of results, one in a Swiss cohort of patients early 2009 and the most recent four-month preliminary trial data indicate that afamelanotide could well become the standard of care as a preventative treatment in (skin) phototoxicity in EPP.

Shortly we will obtain the final results from the placebo-controlled randomised EPP trial (CUV017), which will give us an indication of the safety and efficacy of afamelanotide in 100 EPP patients. Further, we anticipate the successful recruitment of the patients in the confirmatory European EPP trial (CUV029). We are all awaiting the FDA's response to start the clinical program in EPP in the US. Our global teams are continuing the preparation of the EPP program leading up to the US spring, in order to be able to start if and when a positive answer is given. Shortly we will provide further news on this trial (CUV030), and the completion of the confirmatory pharmacokinetic trial in the US (CUV028). Further, Clinuvel is conducting ongoing research and development of afamelanotide with various university centres, and results are expected in 2010.

In summary, I view drug safety as the most important parameter in pharmaceutical development. This is even more relevant when it concerns a novel therapy which has not been subject to prior regulatory review. Maintaining a favourable drug safety profile is perhaps the most critical factor in lowering regulatory risk, as we presented in 2006. The safety profile of a new drug has direct implications for the approval process, one only needs to look at the annual number of new drug approvals (NDA) to obtain a sense of realism. Although all data thus far indicate that afamelanotide is a safe and tolerable drug administered in more than 600 patients in our trials, continuous follow up will further provide proof and add weight to the long term safety of afamelanotide.

Although I am aware of the patience – and at times frustration – we all have to bear in drug development, time is the most important factor assisting regulators to assess afamelanotide as a new drug with long-term safety data. In this respect, the long duration aids us in our quest to obtain a positive marketing review for afamelanotide.

With much energy and optimism I wish our team and loyal shareholders a successful year ahead.

Philippe Wolgen

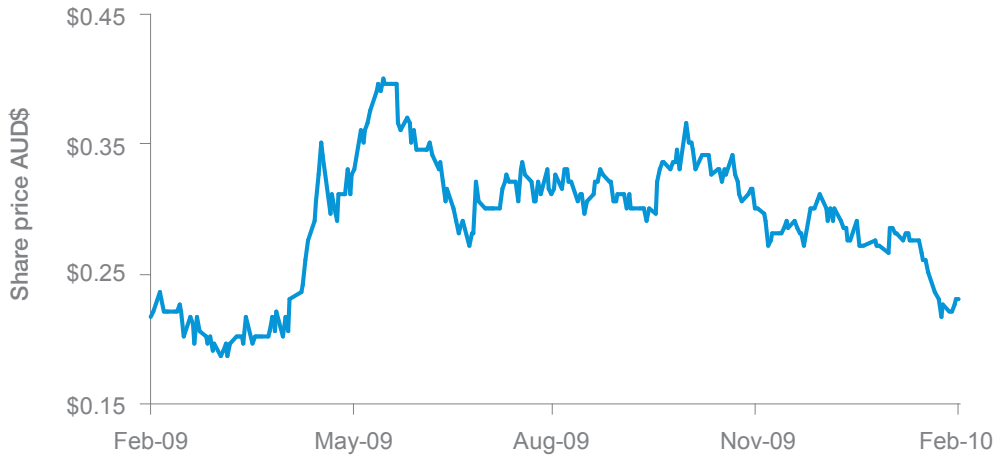
Clinical And Regulatory Timeline

Expected In Q1:

- FDA response on EPP trial in US centres
- Final Results EPP Phase III (CUV017)
- Start EPP confirmatory Phase III trial in EPP (CUV029)
- Final results confirmatory pharmacokinetic trial US (CUV028)

Share Price

Shares on issue
303,168,665
Clinuvel is listed on XETRA (UR9) and has a level 1 ADR (CLVLY)
Average monthly cash burn Oct-Dec '09
<A$1.2m/month
Cash/Asset Balance at Dec 31, 2009
A$32.4million
Average Daily Volume (Past 6 months)
ASX: 334,461



EPP Webcast Videos

To increase awareness and understanding of EPP, two new webcast videos were published alongside the preliminary Phase III EPP results. *Absolute light intolerance: Erythropoietic Protoporphyria* is a brief introduction to the mechanism of EPP and the resulting symptoms in EPP patients.

The second video *"Separate yourself from the pain"* is the result of two days' filming with Adrian, who was diagnosed with EPP at age 5 and now, at 49, is able to reflect on EPP and how it has affected his life. The resulting footage is not only a fascinating insight to EPP, but has resulted in greater global interest in EPP and Clinuvel's program. We are very grateful to Adrian and his family for sharing their story.

To view these webcasts, log onto www.clinuvel.com.

Phase III EPP Preliminary Results

In late December, Clinuvel released preliminary results from our lead Phase III EPP study, CUV017. These results, based on 4-month data from 100 patients, showed that afamelanotide reduced the average number of phototoxic reactions in patients, compared to placebo treatment.

Thirty five patients with severe and/or moderate pain reported the greatest reduction in mean number of reactions (p=0.03, 95% CI). Analysis of pain severity was positively correlated with treatment, indicating that patient pain scores differed significantly between treatment groups (p=0.006, 95% CI).

Importantly, all physicians involved in the trial reported a dramatic improvement in patients' ability to engage in outdoor activity, while the safety profile of afamelanotide remains excellent.

The trial completed in December 2009, with the final patient completing their treatment under the protocol. The team is now collating and analysing the data for final results, due to be completed and announced by the end of March.

The company is still awaiting confirmation from the FDA to commence EPP trials in the USA.

Clinuvel is an Australian biopharmaceutical company focused on developing its photoprotective drug, afamelanotide for a range of UV-related skin disorders resulting from exposure of the skin to harmful UV radiation. Pharmaceutical research and development involves long lead times and significant risks. Therefore, while all reasonable efforts have been made by Clinuvel to ensure that there is a reasonable basis for all statements made in this document that relate to prospective events or developments (forward-looking statements), investors should note the following:

- actual results may and often will differ materially from these forward-looking statements;
- no assurances can be given by Clinuvel that any stated objectives, outcomes or timeframes in respect of its development programme for afamelanotide can or will be achieved;
- no assurances can be given by Clinuvel that, even if its development programme for afamelanotide is successful, it will obtain regulatory approval for its pharmaceutical products or that such products, if approved for use, will be successful in the market place