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Clinuvel Pharmaceuticals Limited
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Clinuvel Pharmaceuticals Limited today announced a fifth medical indication for its drug CUV1647 whereby it may prevent phototoxicity associated with Photodynamic Therapy in cancer therapy. Is this type of phototoxicity a significant problem and is this fifth indication a significant milestone for Clinuvel?

CEO Philippe Wolgen
Photodynamic Therapy, or PDT as it's known, is the fourth most common cancer therapy after surgery, radiotherapy and chemotherapy and all PDT patients suffer varying degrees of phototoxicity as a result of the treatment. PDT patients suffer intense pain when they are exposed to sunlight and are therefore forced to avoid sunlight for up to 90 days following therapy. Clearly this side effect is very limiting in terms of patient activity and PDT's usage.

Recent research has indicated that CUV1647 could be used to prevent phototoxicity associated with PDT and this finding is an important milestone for Clinuvel as it opens up another medical application among a well established and readily identified patient base. How significant a milestone will depend on our trial results. It is early days but it seems clear we've expanded the scope of CUV1647.

With this new indication, CUV1647 now targets two indications related to cancer therapy; PDT and skin cancer in organ transplant recipients. It also targets three indications in UV-related skin disorders: polymorphous light eruption (PLE) likened to sun poisoning; erythropoietic protoporphyria (EPP)

likened to absolute UV intolerance; and solar urticaria that is an anaphylactic reaction to UV radiation.

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Your November 2006 prospectus contains an estimate of A$54 million to fund the clinical program, including the program for continuous product development, costs of clinical trials in PLE Phase II/III, AK Phase II, EPP Phase II/III, and other clinical costs. Will trials relating to the fifth indication add materially to these development costs? Are you still on track with this budget?

CEO Philippe Wolgen
One of the outcomes of finding the PDT indication is that we may accelerate the clinical program and enter larger trials sooner than planned. We're currently adjusting our financial projections which were based on four medical indications. With PDT, as the fifth indication, we'll revisit the budgets to develop CUV1647 to registration.

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Regulatory standards require efficacy and safety be proven in clinical trials in a minimum of 1,000 patients. Will your planned Phase III trials and the completion of all existing trials provide sufficient data to meet this minimum?

CEO Philippe Wolgen
Yes, absolutely. We're planning our entire program in such a way that we'll have the required number of patients to demonstrate the safety of CUV1647. The safety of the photoprotective drug is our main focus in the clinical development program.

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You aim for CUV1647 to be an adjunct treatment in PDT. Can you give some insight into how this would work?

CEO Philippe Wolgen
PDT is a selective cancer therapy, where patients are injected with a dye that has a high affinity to cancer cells. It's a treatment that gains in popularity, to put it in plain terms, in areas where conventional surgery is not desired or possible, or where endoscopic treatment is a preferred option. The use of photo-sensitizers in PDT causes patients to experience prolonged phototoxicity of the skin and eyes for up to 90 days following treatment. These side effects limit the extent that PDT can be used.

We believe CUV1647 could play a role in assisting the cancer patients post-operatively and provide them a post-operative life without photo-sensitivity as a side effect.

An adjunct therapy facilitates and supports existing medical treatments. In the case of PDT as cancer therapy, CUV1647 is intended to prevent the side effects of the photo-sensitisers administered to cancer patients.

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Today's announcement follows results of a Phase II trial of CUV1647 in EPP patients. Is there a connection between the EPP Phase II results and the finding

of this latest indication? Does the EPP trial provide any indication as to the potential of CUV1647 in PDT?

CEO Philippe Wolgen
The symptoms these patients experience are similar to those experienced by protoporphyria patients, a group of patients that we tested in Phase II trials. The underlying pathophysiological mechanism of EPP and the molecules brought out by PDT as cancer therapy are the same.

In general, one can say that EPP is a disease limited to a small group of patients worldwide. Obviously, PDT treats a larger population.

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Do all cancer patients that undergo PDT to treat cancers develop photo-sensitivity? Why are cancer patients so susceptible to photo-sensitivity?

CEO Philippe Wolgen
Yes, all patients that receive photo sensitisers experience phototoxicity to varying degrees. It's the metabolism of these photo sensitisers that brings out chemicals in the skin and eyes.

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Can you quantify the potential market for this fifth indication?

CEO Philippe Wolgen
I believe it is far too early to speak about the commercial implications of the fifth indication. First of all, we must commence clinical trials in relation to PDT patients. What's clear is that we've expanded our scope for CUV1647. We're a step closer to our aim of being a global leader in the use of photoprotective drugs.

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Thank you Philippe.

For more information about Clinuvel Pharmaceuticals Limited, view www.clinuvel.com or contact CEO Dr Wolgen on +61 3 9660 4900.

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