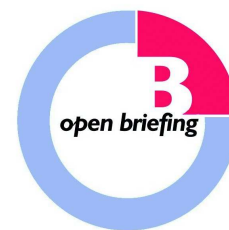


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Clinuvel Pharmaceuticals Limited (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) has announced yesterday that its photo-protective drug, CUV1647, has been granted two ‘Orphan Medicinal Product’ designations by the European Medicines Agency (EMA), for treatment of Erythropoietic Protoporphyrria (EPP) or absolute sun intolerance, and Congenital Erythropoietic Porphyria (CEP). Does “Orphan” designation make commercialisation of CUV1647 more likely?

CEO Philippe Wolgen

We view receiving “Orphan” designations as a firm validation of our path to market in identifying that CUV1647 can be used to treat light related skin disorders such as EPP and CEP. We’re confident that our programmed clinical trials may confirm that EPP can be successfully treated by CUV1647.

Our current Phase III trial for EPP due for completion in 2009 is designed to prove efficacy and safety of CUV1647 in treating this condition. Phase III trial success and subsequent Marketing Authorisation could well drive commercialisation of CUV1647.

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In your announcement, you’ve indicated that completion of the current Phase III EPP trials is expected in 2009. If Phase III trial results are successful, will the two “Orphan” designations assist you in achieving Marketing Authorisation for CUV1647?

CEO Philippe Wolgen

We're certainly better placed to achieve our objective having received "Orphan" designations. In the European Union, all drugs designated as 'Orphan Medicinal Products' must be approved through EMEA's centralised procedures. The designation is, however, not an endorsement of Marketing Authorisation. But this approval could well open up the ability to enter the markets in the EU's 27 member states, conditional on continuous safety of our drug and positive Phase III results.

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Can you explain the nature of EPP, currently being tested in Phase III trials? Also, can you briefly explain the nature of CEP?

CEO Philippe Wolgen

EPP is a rare genetic disease found in people with fair skin. It is characterised by severe light-sensitivity or "phototoxicity" of the skin resulting in intolerable pain, swelling, and scarring, usually of the hands and face, so the areas exposed to UV and light. The pain suffered by an EPP patient when their skin is exposed to light is comparable to that caused by scalding boiling water on the skin. EPP patients are often forced to remain indoors, severely affected in their inability to lead a normal life or as put in medical terms: a condition severely affecting their quality of life. Our photo-protective drug CUV1647 increases melanin density (biological pigmentation) in the skin through a controlled release resorbable implant thus shielding the skin from the damaging effects of the sun. In essence, through our drug CUV1647 we're able to switch on nature's own pigment without exposing the skin to the sun and its damaging effects. We administer CUV1647 to test in our trials whether the drug can assist sufferers of this rare disease.

Also known as Guenther's disease, the causes of CEP are similar to EPP. CEP is an extremely rare disease found in people with fair skin with patients experiencing extreme photosensitivity resulting in blistering, severe scarring and increase hair growth. Infection of damaged skin and phototoxic damage may result in the loss of fingers and facial features. The Committee for Orphan Medicinal Products (COMP) has included this disease as it is thought that any treatment with CUV1647 would be potentially useful to prevent severe skin blistering and wound formation. In fact, we are conducting a trial in CEP already.

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What does an "Orphan" designation mean for the launch time of a drug generally?

CEO Philippe Wolgen

European orphan drug incentives have resulted in significant interest and development activity in orphan diseases across the pharmaceutical and biotechnology industry. Many pharmaceutical companies have successfully used protocol assistance to help overcome some regulatory hurdles and ultimately expedite the time to launch new drugs.

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What is the relevance of the diverse regulatory strategy?

CEO Philippe Wolgen

A single compound or drug in development may receive more than one “Orphan” indication. Our regulatory strategy for CUV1647 has identified several indications to apply for an “Orphan” designation: EPP, CEP and possibly one other in Solar Urticaria. The first two have now finally been achieved.

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What if you want to use CUV1647 for a broader indication?

CEO Philippe Wolgen

Follow-on indications for CUV1647, such as Polymorphic Light Eruption (PLE), which is severe sun poisoning and skin cancer, may broaden out the treatment base beyond the “Orphan” indication. At the same time, the drug will enjoy much of its ten years of market exclusivity in its current treatment settings. Any indication outside the scope of the “Orphan” designation will have to undergo the process of approval through a separate Marketing Authorisation Application (MAA).

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What examples are there of “Orphan” drug designations?

CEO Philippe Wolgen

Amgen’s Epogen® is the world’s leading orphan drug by worldwide sales. Looking at the high end of the market, analysts estimated that Epogen® achieved sales of \$2.4 billion in 2007. There are over nine medicinal products with sales over \$1 billion each, designated as orphan drugs in the US. Amgen markets three and Johnson and Johnson markets two of these. European examples include Genzyme’s Fabrazyme® (targeting alpha-galactosidase deficiency) and Novartis’ Glivec® (used for the treatment of a rare form of leukaemia). At the other end of the market, other orphan drugs have made an impact too, although sales are not as impressive. Most of all, it is the ability to offer a treatment to patients who have no other resort for their disease.

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How many EU “Orphan” designations are given annually?

CEO Philippe Wolgen

There is an average of 59 designations approved per year. The EMEA website lists all “Orphan” drug designations granted since 2000. A few hundred have been approved since that time, with twelve refused and 35 suspended. The progression rate to successful Marketing Authorisation is reported to be around two thirds.

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What are the differences between a European and US “Orphan” designation?

CEO Philippe Wolgen

The addition of a designation for showing 'significant benefit' in EU regulations adds a greater chance for novel therapies development.

There is a significant difference in the budgets of the respective orphan drug programs in the US and EU, with US budgets far outweighing those in the EU.

The US waives user fees for “Orphan” drugs and a waiver for annual product fees can be requested. There is also a well-established tax credit system in the US, which is very difficult to implement in the EU as the Member State tax systems are diverse. Grants to fund the clinical program for orphan drugs are also accessible in the US. Protocol assistance is offered in both jurisdictions; however, typically it is more likely to be used in the US. We intend to use this option to assist us with the regulatory process.

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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

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