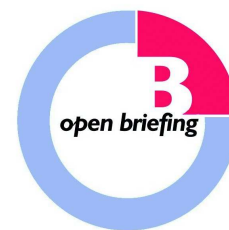


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Clinuvel Pharmaceuticals Limited (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) recently announced that the US Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to its photoprotective drug, afamelanotide (CUV1647) for the treatment of erythropoietic porphyrias. What does this designation mean for the commercialisation of afamelanotide?

CEO Philippe Wolgen

The Orphan Drug Designation by the US FDA provides an incentive to drug companies to commercialise new therapies for severe and rare disorders. In this respect, we see the designation as recognition of our development path to market by the FDA. Earlier this year, we obtained orphan drug status from the European Medicines Agency (EMA) and Swissmedic.

The regulatory approval process – pending the ongoing safety of afamelanotide (CUV1647) – is now more or less mapped out. While the drug continues to exhibit its pharmacological action, one could say that commercialisation has now become a function of our execution and ability to test the drug in the required amount of patients.

However, the worldwide management of an orphan indication is far from simple and still bears risks. Physicians and patients remain our most precious assets for Clinuvel to be successful in our efforts to commercialise afamelanotide.

Recognition from regulatory authorities on both sides of the Atlantic is a big step towards our ultimate goal of commercialisation. It is a real positive for our shareholders and gives us confidence in our strategy to commercialise afamelanotide.

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In your recent announcement, you mentioned that the next major step is to obtain US FDA Investigational New Drug (IND) status in order to conduct trials in erythropoietic porphyrias. If the IND approval is successful, how will you be funding your trials in erythropoietic porphyrias in the US? Are you considering applying for a clinical research grant through the Office of Orphan Products Development?

CEO Philippe Wolgen

The current statistics demonstrate that the FDA is looking at novel drugs more critically than ever. According to the FDA, there were only 17 new approvals for new molecular entities (NMEs) by the FDA in 2007. This has declined about 60 percent over 10 years. One of the 17 NMEs granted is designated as an orphan drug as an advance over available therapies, while two NMEs are designated orphan drugs that appear to have the same therapeutic qualities as a drug that is already marketed.

In afamelanotide, we identified a first-in-class drug which delivers novel pharmaceutical activity. We anticipate and plan to file for our first IND this year, 2008. Much technical work to generate compelling data on the drug and formulation has been done over the past 10 months to compile a dossier that meets US regulatory standards. Our one and only goal is to build a dossier that will be robust enough to withstand critique by US FDA examiners, all set against background of stricter regulatory review process.

We have the cash reserves to fund the EPP trials in the US. Our cash position as at June 30th was \$50.8 million, which represents 50.8 percent of our current market capitalisation of \$100 million based on our current share price of \$0.33. Our liquidity position is sound. If Clinuvel is eligible to obtain a US grant, we will certainly apply; however, the first analysis has learned that Clinuvel probably does not qualify for this support.

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What financial benefits will you receive from this FDA ODD approval?

CEO Philippe Wolgen

There are a number of financial benefits in the US, which include tax relief for the costs of clinical research, assistance in regulatory application fees and clinical research study designs and special protocol assistance. The ODD approval also waives the Prescription Drug User Fee Act (PDUFA) filing fees which is about US\$1 million per application for 2008.

The incentive that is probably of most interest to our investors is the seven years market exclusivity in the US that comes with the orphan-drug designation; in Europe it is a 10 year exclusivity shielding from generic or any competitive pressure. This period of exclusivity could prove to be a strong value driver.

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Afamelanotide received 'Orphan Medicinal Product' designations recently from the EMEA and Swissmedic for the treatment of Erythropoietic Protoporphyrin (EPP) and Congenital Erythropoietic Protoporphyrin (CEP). What was the strategic rationale of applying for the ODD status in the US? How will this designation assist you in achieving Marketing Authorisation for afamelanotide in the US?

CEO Philippe Wolgen

We potentially have identified the opportunity to innovate the management of porphyrias through afamelanotide as a photoprotective drug. Porphyria patients give an account of isolated lives, and thus far have no means to manage phototoxicity; the pain described by these patients is hard to imagine.

Our objective is to develop a new molecular entity (NME) for diseases to which patients have tried all other alternatives or have not found either medical therapy or relief at all. Innovation and the ability to offer new treatment is ultimately what one aspires to leave behind in the pharmaceutical industry. In my view, this objective should be the only driver to withstand the pressures in this industry and offers the best chance of successfully obtaining Marketing Authorisation in any market, including the US.

Regulators, such as the FDA, review a new drug on clinical data and safety first, subsequently arrive at an outcome by utilising risk benefit models. With last Tuesday's FDA Orphan Drug Designation, Clinuvel stands a fair chance of obtaining an IND approval and subsequently Marketing Authorisation or New Drug Application (NDA), albeit pending positive clinical results.

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Placebo controlled trials (Phase III) are underway in Europe in relation to Erythropoietic Protoporphyrin (EPP) for afamelanotide. When will you complete the trials and what are the likely future steps for the advancement of afamelanotide in relation to EPP in Europe?

CEO Philippe Wolgen

The third cohort of European patients is being administered afamelanotide at present, and by December we anticipate having approximately 80 EPP patients in the clinical trials. Geography and willingness of the patients to participate in a clinical trial are some of the hurdles we have to overcome in developing afamelanotide in EPP.

The trial size is excellent for an orphan disease as EPP affects one in 200,000 people in the world, and our team has done well in this respect. We aim to complete the trials in the third quarter of 2009. We will file for marketing approval in Europe shortly after, upon positive results and proven clinical safety of afamelanotide.

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Will you be applying for Orphan Drug Designation for other indications of afamelanotide in either the US or Europe?

CEO Philippe Wolgen

If you look at the five indications where afamelanotide is being administered, we would probably have the option to apply for one more orphan-drug status. However, only when we've proven that the drug is of clinical benefit in another rare disorder, would we contemplate filing for ODD for other indications. For now, we don't see the immediate benefit of filing for ODD for other indications of afamelanotide.

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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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