



Clinuvel communications

Live on Clinuvel.com today: 1. Clinuvel announces positive results in Phase II Solar Urticaria study
2. Podcast with CSO Dr Hank Agersborg

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Series I: Technical Note to the company announcement

Wednesday 15th July 2009
Melbourne, Australia

Results: Phase II open-label trial in Solar Urticaria (SU)

Afamelanotide in SU

Clinuvel is focusing its resources on the pharmaceutical development of afamelanotide as a slow-release formulation for the prevention of UV and light related skin disorders. Those who have followed the company over the years are aware that Clinuvel's challenge is to develop skin protection against environmental factors such as UV.

SU is an acute and recurrent disease whose etiology is unknown. Symptoms are triggered by exposure to light and UV, predominantly in spring and summer. Typically, 'flares' and 'wheals' are seen on the areas of exposed skin. In professional terms, SU is seen as an IgE-mediated immune response (where light acts as allergen causing antibody formation). Treatment is very limited and in severe cases patients may receive the most invasive treatment in the form of plasmapheresis (purification of blood plasma). SU is classified by dermatologists as a serious and rare disease, where prevalence is estimated at 3-4 per 100,000 people. In those affected, the quality of life is significantly compromised by their restricted ability to participate in normal outdoors activities.

Results - Manchester trial in Solar Urticaria

The positive results announced today originate from a pilot study of 5 severe SU patients at Hope Hospital in Manchester, UK. The objectives were to test the photoprotective effects of afamelanotide in fair-skinned SU patients. When comparing the patients' response to various wavelengths of light before and after administration of afamelanotide, all patients experienced a significant increase in skin tolerance to light and UV irradiation without any anecdotal outbreak of SU symptoms.

The relevance of these results lies in afamelanotide's potential to offer prevention of symptoms to SU patients. We are now encouraged to evaluate afamelanotide in SU under ambient conditions in spring and summer. This trial will comprise of approximately 40 patients starting in March and ending in September 2010. SU will be the second 'orphan' indication for which Clinuvel will apply for marketing authorisation of afamelanotide.

Human pigmentary response and afamelanotide

In the past decade significant progress has been made in understanding the short and long term damage of light and UV to the skin. It is well established that pigmentary response is a human physiological reaction to cellular damage; in other words melanogenesis (pigment production) is our ultimate means of limiting further damage from 280 to 500 nm wavelengths of light (UV and beyond). Although the physiological hormone alpha-MSH is the main hormone to regulate pigmentary response, most fair-skinned individuals lack an ability to activate skin's melanin effectively and are at risk of contracting skin cancer and other disorders, such as SU.

This has made Clinuvel's clinical progress of universal interest. After a decade of development where various changes have been made to the drug and delivery, Clinuvel's proprietary drug product, afamelanotide, has proven to assist and compensate for the lack of natural skin protection in patients with a fair complexion (skin type I and II Fitzpatrick classification). As widely published, afamelanotide will be developed for patients with the most serious conditions affecting their ability to expose themselves to a normal outdoors life. The patients suffering from porphyrias (EPP and CEP) and SU are most critically affected by light and UV. It is for these indications that the

Clinuvel team initially intends to develop afamelanotide. Other diseases may benefit from afamelanotide (see www.clinuvel.com).

Counterfeit Markets

As is seen with many first-in-class pharmaceuticals, vendors globally - aiming at short-term gains - seek to bypass decades of regulated pharmaceutical drug development by offering cheap and untested chemicals on market. The ability to reach a global audience online has opened up new channels for rogue traders.

Clinuvel has seen the past years the emergence of illegal products offered over the internet under the name of 'Melanotans'. Contrary to the online claims, these illegal chemicals do not bear any resemblance to afamelanotide in chemical composition or formulation, while scientific results produced by Clinuvel are being used by these vendors to justify and bolster their sales. Most counterfeit chemicals marketed as Melanotan I and II come out of the US and China from shady laboratories and present misleading claims to the general public. In essence, these products pose a hazard to health short and long term.

In the e-world, responsibility has shifted predominantly to consumers, as sole manufacturers and vendors escape product liability. Consumers and e-shoppers are asked to resist the temptation of using and injecting themselves with illegal and untested chemicals. It is absolutely clear that the ignorance and naivety of so-called chemical entrepreneurs is at the expense of online shoppers.

I strongly warn against the use of untested chemicals, which are often sold as safe 'injectable tanning products'. Self-injecting impure and untested chemical substances available online is unsafe and a disrespect to one's own life at best, while the first cases of illness have recently been reported.

US FDA and European EMEA

My recent experience with pharmaceutical regulators FDA and EMEA is a most positive one where these institutions have become forensic experts seeking to eliminate rogue trades in order to protect public health as well as companies seeking to develop breakthrough treatments.

In times where the first medical victims are reported, it is of value to recall that the foundation of the pharmaceutical industry is based on the scientific challenge to find innovative drugs and therapies, whereby this process remains a highly regulated one with a median development cycle of 10 years to bring a new drug to market. With global capital markets able and willing to fund these companies, it is deplorable that unqualified manufacturers and vendors seek to exploit consumerism. With my deep belief in the efficiency of an online world, I am confident and optimistic that the e-message will travel swiftly to bring rogue manufacturers and traders to justice.



Dr Ph Wolgen MBA, MD
CEO, Clinuvel Pharmaceuticals Ltd

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

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