# Biotech Daily's CEO interview

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**'CUV1647 NOT A COSMETIC, NOT A SUNBLOCK'**
**– CLINUVEL'S DR PHILIPPE WOLGEN**

CLINUVEL'S CHIEF executive officer Dr Philippe Wolgen has forcefully rebutted analyst, investor and media misconceptions about his company's lead drug CUV1647.

Dr Wolgen told Biotech Daily today that he would have nothing to do with developing a systemic drug for the cosmetic market, a belief held by some biotechnology industry specialists about the compound first developed as Epitan's EPT1647.

"This will not be a cosmetic drug," Dr Wolgen said. "I oppose systemic treatment for cosmetics."

He said the cosmetic market was subject to fads and it was not appropriate to go through the demands of the Australian Therapeutic Goods Administration and the US Food and Drug Administration processes for a cosmetic drug which may be out of favor before registration was completed.

The French-born Dr Wolgen who qualified as a medical doctor in the Netherlands and also holds an MBA admitted he had a difficult task turning around investor and analysts opinions of a company that had been around for as long as Clinuvel and Epitan. He said Epitan had a compound that was safe and worked to increase melanin levels.

In the restructure that led to the change in company name and his appointment as chief executive officer in November 2005, Epitan decided Clinuvel would become more clearly focused on the drug described by chairman Dr Roger Aston as "a potential blockbuster which will feature on a global stage".

The market has welcomed the changes with Clinuvel's share price rising significantly from 30 cents 12 months ago to its current price of more than $1.15.

Dr Wolgen noted that companies that have a share price explosion can fall just as rapidly.

He says some investors still ask whether CUV1647 has cosmetic applications and are disappointed when he says "No."

On a separate issue raised by industry specialists, Dr Wolgen strongly rebuts claims that CUV1647 is a sun-block substitute.

He says that when administered correctly sun-blocks can be effective against ultra-violet A and B light with wavelengths from 280-400 nanometres, but are not effective against longer wavelength, deeper penetrating light from 410-700 nanometres.

"Sunscreen doesn't work for [erythropoietic protoporphyria] because it is ineffective for the higher wavelengths," Dr Wolgen said.

While the number of potential erythropoietic protoporphyria (EPP) patients is small at about 1200 to 1400 in the US, much larger target markets are

found in patients receiving photodynamic therapy who are photosensitive or phototoxic and transplant patients.

In the former group, patients having tumors burnt out by laser-like light, the dye that identifies the tumor makes the patient photosensitive or phototoxic and it lasts in their systems for up to 90 days. The choice is to remain fully covered outdoors, stay inside or - if proven in clinical trials and granted regulatory approval - be given CUV1647 to raise their melanin levels, increasing their photo-protection.

Another large patient group is fair-skinned transplant patients who are immuno-suppressed – a key focus group for CUV1647.

Dr Wolgen said he would never propose CUV1647 as a substitute for sun-block, but for people prone to skin cancers and sun sensitivity or toxicity they could use both a topical sun-block and CUV1647, when it is formally approved.

He said sunlight can cause intolerable pain to some people “within minutes”.

CUV1627 is currently in phase III trials for polymorphous light eruption (PLE), has received approval for a phase III trial for EPP and is in phase II trials for squamous cell carcinoma and actinic keratosis in organ transplant patients and for solar urticaria.

Clinuvel closed unchanged at $1.20.