Company Announcement

Five month study follow up shows SCENESSE® combination treatment provided stable repigmentation in vitiligo patients

A follow up of the first Phase II vitiligo study (CUV102) showed that depigmentation had not recurred in patients treated with a combination therapy of SCENESSE® and narrowband UVB (NB-UVB)

RESULTS SUMMARY:

- Repigmentation of patients following treatment with SCENESSE® was higher than with the NB-UVB group at 11 months since start of the treatment [p=0.032; 95% CI]
- Repigmentation for the combination group was maintained at the 11 month follow up; vitiligo did not reoccur
- No safety concerns were identified during combination treatment
- Three academic heads of departments reported excellent overall results from CUV102 trial

Baar, Switzerland and Melbourne, Australia, September 2 2013

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced follow up results from its study of the drug SCENESSE® (afamelanotide 16mg) as a combination therapy with narrowband ultraviolet B (NB-UVB) in the pigmentary disorder vitiligo. Analysis from the study (CUV102) showed that repigmentation achieved in vitiligo patients who had received combination therapy with SCENESSE® and NB-UVB had proven stable for 11 months since the start of the treatment. Final efficacy results were published on December 19 2012.

ABOUT VITILIGO

Vitiligo is a skin disorder, affecting approximately 45 million people, in which particular pigment producing cells of the skin (melanocytes) appear to become dysfunctional. As a result, lighter depigmented patches of skin (lesions) appear in different parts of the body due to the loss of melanin (pigment). Vitiligo therapy is primarily intended to arrest depigmentation and to stimulate repigmentation of affected skin as a secondary action. There is no known cure for vitiligo. The current standard of care is treatment with NB-UVB, a controlled light therapy given in 2 to 3 sessions per week over the course of 12 to 18 months. The response rate to NB-UVB is low and repigmentation is incomplete. Combination therapies are often employed in an attempt to enhance repigmentation.

Of those vitiligo patients who experience initial success following treatment with NB-UVB, many suffer a recurrence of depigmentation following cessation of therapy, which is recognised as a major clinical challenge in treating vitiligo.

RESULTS

In total, 41 patients (75.9%) of the 54 recruited for this trial had completed the treatment at Day 168 and 35 patients (64.8%) had presented for follow up at Day 336. Total body pigmentation at the completion of the treatment period (Day 168) was compared to Day 336 using the VASI scale (a standard clinical measurement for vitiligo).

Repigmentation of vitiliginous lesions in patients who had received the combination treatment of SCENESSE® together with NB-UVB was higher at each time interval (Days 224-280-336) than the NB-UVB group alone (respectively p=0.025; 0.037; 0.032, CI 95%).

Of clinical significance were the results found in patients with darker skin complexion (Fitzpatrick skin types IV-VI). Although vitiligo affects patients of all skin types, those with darker skin complexion are often the most stigmatised due to the visible contrast between vitiligineous lesions and dark skin. Analyses of VASI scores at days

224, 280 and 336 in patients with skin types IV to VI showed that the combination therapy was more effective than NB-UVB alone (respectively p= 0.049; 0.049; 0.047, CI 95%).

At the final follow up visit at Day 336, the safety of the combination therapy was assessed and no significant treatment-related adverse events were reported by either patients or physicians. All patients who received SCENESSE® reported at follow up visit that it had been well tolerated.

DISCUSSION

With the introduction of a new treatment in vitiligo, it is important during Phase II trials to establish whether patients experience repigmentation that is stable and sustainable. Current vitiligo treatments provide a modest and variable pigmentary response. However, much variability exists in the duration of treatment needed to achieve the current clinical results. The regimen of NB-UVB radiation administered 2 to 3 times weekly for up to 18 months poses a significant burden to patients and physicians, and has an impact on healthcare spending. An improvement in the intensity and extent of repigmentation and a reduction in the treatment time would be clinically valuable.

“Vitiligo is notoriously difficult to treat and it’s frustrating when patients see pigment loss after treatments which may take months,” said Dr Pearl Grimes, Director of the Vitiligo & Pigmentation Institute of Southern California, Clinical Professor, Division of Dermatology, UCLA, and an investigator in the CUV102 study. “What we’ve seen with SCENESSE® is that, compared with narrowband monotherapy, vitiligo patients see improved repigmentation in a shorter timeframe and this pigmentation is maintained.

“After more than 30 years of treating vitiligo, I’m excited that we may have a new drug, and one with a very encouraging risk-benefit profile, for our patients,” Dr Grimes said

“We are encouraged by the overall results, particularly the feedback we have received from the study investigators,” said Clinuvel’s acting Chief Scientific Officer, Dr Dennis Wright. “These results, together with the earlier efficacy analyses show that SCENESSE® has the potential to become the main pharmaceutical agent used in the treatment of vitiligo.”

“In the next trial we will focus our attention on the repigmentation in patients with darker skin complexion because vitiligo is most conspicuous and has a large social impact in these patients. Developing a treatment for these patients will be rewarding since the loss of pigmentation is described by these patients as a loss of their identity,” Dr Wright said.

Clinuvel expects an Asian Phase IIb study of SCENESSE® in vitiligo will to commence before the end of 2013, subject to regulatory approval.

About SCENESSE® (afamelanotide)
SCENESSE® is a first-in-class therapeutic being developed by Clinuvel, with the generic name (or INN) afamelanotide. An analogue of α-MSH, afamelanotide is a linear peptide which activates eumelanin of the skin, the dark pigment which is known to provide photoprotective properties (offering skin protection against light and UV radiation). SCENESSE® is administered underneath the skin as a dissolvable implant approximately the size of a grain of rice. For more information on SCENESSE® go to http://www.clinuvel.com/en/scenesse.

SCENESSE® is a registered trademark of Clinuvel Pharmaceuticals Ltd.

About Clinuvel Pharmaceuticals Limited
Clinuvel Pharmaceuticals Ltd (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) is a global biopharmaceutical company focused on developing drugs for the treatment of a range of severe skin disorders. With its unique expertise in understanding the interaction of light and human skin, the company has identified three groups of patients with a clinical need for photoprotection and another group with a need for repigmentation. These patient groups range in size from 10,000 to 45 million. Clinuvel's lead compound, SCENESSE® (afamelanotide), a first-in-class drug targeting erythropoietic protoporphyria (EPP), has completed Phase II and III trials in the US and Europe.

In February 2012 SCENESSE® was filed for review by the European Medicines Agency for EPP. A confirmatory six month Phase III US EPP trial commenced in May 2012. Presently, there is no known effective treatment for EPP and SCENESSE® has been granted orphan drug status. Based in Melbourne, Australia, Clinuvel has operations in Europe and the US.

For more information go to http://www.clinuvel.com.

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