Company Announcement

Thursday 3rd March 2011
Baar, Switzerland and Melbourne, Australia

FDA allows Clinuvel's innovative vitiligo trial

US- European INSPIRE trial to begin at leading global centres

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that the US Food and Drug Administration (FDA) has allowed the company to proceed under its current Investigational New Drug (IND) to conduct a pilot Phase II clinical trial (CUV101) of its drug afamelanotide (known as SCENESSE®) in patients diagnosed with nonsegmental vitiligo.

The trial is the first time SCENESSE® will be tested as a repigmentation therapy in nonsegmental vitiligo, a pigmentary disorder affecting over 45 million individuals globally, as part of Clinuvel's INSPIRE (**In**ternational **S**CENESSE® **Pi**lot **R**epigmentation **E**valuation) program.

Vitiligo is a disease which causes white or off-white depigmented skin lesions to appear on different parts of the body due to a loss of melanin (pigment) production. This disorder may spread over time and cause patients significant psychological and emotional distress. The exact cause of vitiligo is unknown, but it is generally recognised that an autoimmune component plays a role in the disease.

In accordance with the provisions of Code of Federal Regulations (CFR) Title 21 Part 312 (21 CFR 312), the FDA allowed Clinuvel to proceed with its clinical evaluation of SCENESSE® in nonsegmental vitiligo.

Trial design

CUV101 is a multi-centre six-month open label pilot study to evaluate the efficacy of SCENESSE® as a combination therapy with narrowband ultraviolet B (NB-UVB) phototherapy compared to NB-UVB alone. The goal of the trial is to determine whether SCENESSE® will reduce the total dose of radiation (NB-UVB) and the time required to reactivate skin pigment producing cells in vitiliginous lesions. NB-UVB clinically administered thrice per week over 18 months is considered the standard of care in nonsegmental vitiligo to prevent the progression of lesions and stimulate repigmentation in depigmented skin.

SCENESSE® will be administered every 28 days to 50 percent of the trial patients. All trial patients will be treated with NB-UVB thrice weekly for six months (72 treatments total) and repigmentation and maintenance of pigmentation will be evaluated using the internationally recognised Vitiligo Area Scoring Index (VASI) and Vitiligo European Task Force (VETF) evaluation system. Overall results between the group treated with SCENESSE® and the NB-UVB only group will then be compared. For six months following the completion of the dosing each patient will attend three clinical visits to allow long term comparison of the repigmentation effects of the two treatments.

The trial will be conducted in six expert vitiligo centres – three each in the US (California, Michigan and New York) and Europe (France, Italy and Switzerland) – with each centre recruiting up to 20 patients. US patients will commence the study in the second week of March. The Italian regulatory agency (AIFA) has approved the study following local ethical committee approval. Clinuvel has made submissions to the Swiss and French regulatory agencies and is awaiting their response.

Comment

"Following a stringent review of our proposed protocol with world leading vitiligo experts and a submission to the FDA we can now progress with this much awaited study," said Clinuvel's Chief Scientific Officer, Dr Hank Agersborg.

“This is an historic trial in dermatology, as there has really not been an effective therapy for these patients. For Clinuvel it is the first time we will administer SCENESSE® to treat a disease rather than as prophylaxis. The combination therapy with narrow-band UVB is very promising.”

“Vitiligo is an exciting new therapeutic area for Clinuvel and one which we prepared for years with the selected centres of excellence. From a biochemical point of view, the use of SCENESSE® makes much sense. Narrowband UVB induces melanocortin-1 receptor status in differentiating pigmentary stem cells at deep levels of the skin. Subsequent administration of SCENESSE® should aid the pigment cells to produce pigmentation by restarting the cellular machinery,” Dr Agersborg said.

“From a commercial point of view, our shareholders should be pleased that the lengthy development program has led to this indication with significant market potential,” added Clinuvel’s Chief Executive Officer, Dr Philippe Wolgen.

“The initial response that the company has received from vitiligo patients to participate is a true indication of the severity and need for an effective therapy in this disorder,” Dr Wolgen said.

Trial participation
Due to significant global interest in the INSPIRE program from vitiligo patients, Clinuvel has published further details on trial participation on its website, available at http://www.clinuvel.com/vitiligo.

- End -

Appendix I (Following Code of Best Practice, ASX)
Name of trial
CUV101 A Phase II, Randomised Pilot Study to Compare the Efficacy and Safety of Subcutaneous, Bioresorbable Afamelanotide Implants and Narrow-Band Ultraviolet B (NB-UVB) Light in the Treatment of Nonsegmental Vitiligo.

Primary objective
a) To compare the efficacy of afamelanotide implants and NB-UVB light in the treatment of nonsegmental vitiligo

Secondary objectives
a) To determine the short-term safety of both treatments in patients with nonsegmental vitiligo
b) To compare the maintenance of pigmentation achieved with both treatments in patients with nonsegmental vitiligo

Blinding status
Open label.

Product development status
Good Manufacturing Practice (GMP) Standard.

Number of trial subjects
Up to 120 patients (up to 20 per trial site).

Subject selection criteria
- Male and female subjects with a confirmed diagnosis of nonsegmental vitiligo with 15% to 50% of total body surface involvement
- Stable or slowly progressive vitiligo over a 3-month period
- Patients previously untreated with any kind of light therapy (including NB-UVB)
- Aged 18 or more
- Fitzpatrick skin types III-VI

Trial location
Six trial sites: three each in the US (California, Michigan and New York) and Europe (France, Italy and Switzerland)

Expected duration of the trial
Twelve months: six month treatment for an individual patient with a six month follow up period.

Trial standard
In compliance with Good Clinical Practices (GCP) and ICH guidelines.

Appendix II About Clinuvel Pharmaceuticals Limited
Clinuvel Pharmaceuticals Ltd is a leading and innovative Australian company focused on the development of SCENESSE® (afamelanotide), its proprietary first-in-class photoprotective drug. Clinuvel has identified a number of groups of patients with a clinical need for photoprotection and one with a need for repigmentation therapy. Currently, Clinuvel is in its final stages to complete testing of SCENESSE® in Phase II and III trials in Australia, Europe and the United States. Clinuvel's ongoing focus is to demonstrate the safety and efficacy of SCENESSE®. Pending positive clinical results, Clinuvel aims to file SCENESSE® for its first market approval for the orphan indication porphyria (EPP).

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

About vitiligo
Vitiligo is a common skin disorder in which the pigment producing cells of the skin (melanocytes) are absent or demonstrate lack of activity. As a result, lighter depigmented patches of skin (target lesions) appear in different parts of the body due the lack of melanin (pigment). The exact cause of vitiligo is unknown, but it is generally recognised that an autoimmune component plays a role in this disease. Between 0.1-2% of the global population is affected by vitiligo, affecting all races. Vitiligo causes significant psychological and emotional distress.

Vitiligo is traditionally separated into two clinical forms: nonsegmental, or generalised, vitiligo (NSV) and segmental vitiligo (SV), which present with distinctive clinical features and natural histories.

NSV is the most common form of the disease, accounting for 72-95% of the cases. The vitiliginous lesions are usually symmetrically distributed and new patches may appear throughout the patient's life. The disease is progressive with flare-ups. NSV is frequently associated with personal or family history of auto-immunity.

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Clinuvel is an Australian biopharmaceutical company focussed on developing its photoprotective drug, SCENESSE® (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 SCENESSE® can or will be achieved;
- no assurances can be given by Clinuvel that, even if its development programme for SCENESSE® 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