Company Announcement

Wednesday 25 August 2010
Melbourne, Australia

Clinuvel to evaluate SCENESSE® as therapy in vitiligo

Pilot study to evaluate drug in pigmentary disorder affecting more than 45 million globally

Clinuvel Pharmaceuticals Limited (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) today announced that it will begin a pilot trial (CUV031) with its first-in-class drug SCENESSE® (afamelanotide) as a repigmentation therapy in the pigmentary disorder vitiligo. The trial will focus on patients diagnosed with nonsegmental vitiligo (NSV), the most common form of the disorder which affects approximately 45 million people globally.

During an investigators' meeting on 21 August in New York, Clinuvel reached agreement with four of the world's most prominent and expert centres specialising in vitiligo. Consensus was reached on the protocol and study design. The trial is scheduled to start in October, subject to obtaining the necessary European and US regulatory approvals.

SCENESSE® as repigmentation therapy in nonsegmental vitiligo

SCENESSE® is a first-in-class and innovative drug being developed exclusively by Clinuvel. The drug has been tested in approximately 550 patients in regulated clinical trials. SCENESSE® acts by increasing melanin levels in the skin attempting to shield against UV radiation (UVR) and sunlight. The drug is delivered by a small subcutaneous implant approximately the size of a grain of rice. Increased pigmentation of the skin begins to appear two days after implantation and lasts for up to two months.

This trial will evaluate SCENESSE's ability to repigment areas of skin with and without the use of narrowband ultraviolet B (NB-UVB) phototherapy.

Phototherapy, mainly narrow band UVB (NB-UVB), has emerged as a mainstay of repigmentation treatment in individuals affected by vitiligo. NB-UVB utilises a localised light source to activate melanin in vitiliginous lesions of the skin. This therapy is known to effectively suppress the local immune response and accelerate the maturity of melanocytes in the area around hair follicles, which act as melanocyte reservoirs. This process leads to activation of melanin (pigment). Data from this pilot study will give Clinuvel insight into whether SCENESSE® as monotherapy is preferable to NB-UVB alone or whether the two treatments combined provide a superior clinical result.

Commentary

Clinuvel's Chief Scientific Officer, Dr Hank Agersborg said:

"In this study we seek to evaluate SCENESSE® in perhaps in the most logical indication of all, nonsegmental vitiligo, a disease in which there is a reduction in functional activity of melanocytes. There is great expectation from the leading scientific experts in the field that SCENESSE® could actually better the currently inadequate treatment. The two US and two European centres selected are among the most advanced in the treatment of vitiligo."

Clinuvel's CEO, Dr Philippe Wolgen said:

"The breakthrough in our thinking is as meaningful as the choice we made to make SCENESSE® available in vitiligo.

“About two years ago the first long-term results from phototherapy in vitiligo were seen. Frequent sessions of NB-UVB showed that repopulation of pigment producing cells either from the periphery or from the roots of the hairs in the skin was possible. This alone was a breakthrough, as previously it had always been thought that repigmentation of vitiligo was impossible, now we know that partial repigmentation is clinically possible with the assistance of narrowband UVB.

“Naturally, these academic developments piqued our interest, and we soon understood that the re-emergence of melanocytes in vitiligo would offer the pharmacological basis for SCENESSE® to assist, and possibly reduce, the doses of phototherapy.

“It is again clear that SCENESSE® attracts attention from the clinical and academic communities worldwide and, after years of clinicians petitioning for the drug to be used in vitiligo, Clinuvel has now found sufficient evidence to support the use of the drug in vitiligo. For patients and shareholders, today’s announcement marks one of the most exciting directions for Clinuvel.”

Vitiligo

Vitiligo is a common skin disorder in which the pigment producing cells of the skin (melanocytes) are absent or inadequate. 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 part in this disease. Between 0.1-2% of the global population is affected by vitiligo and it affects 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.

SV is characterised by a unilateral distribution that may totally or partially match a dermatome (area of skin with innervation from a single spinal nerve) and has an earlier onset and a rapid spread. It may account for 30% of childhood cases. Auto-immune association is rare with SV.

Vitiligo therapy is intended to arrest depigmentation or provide repigmentation of depigmented lesions. Many treatment options exist but many clinical challenges persist. Not all patients respond to available therapies and relapse is common.

Clinuvel's clinical focus for SCENESSE®

Nonsegmental vitiligo (NSV) will be the sixth indication to be clinically evaluated by Clinuvel for the novel drug SCENESSE®.

The company continues to advance its program for the rare light intolerance erythropoietic protoporphyria (EPP) in Phase II and III confirmatory trials in the USA and Europe. respectively. Positive results were announced from the first Phase III study of SCENESSE® in EPP in July 2010. Further trials continue to evaluate SCENESSE® as a photoprotective drug in Europe for patient with severe polymorphic light eruption and in Europe and Australia as a preventative for certain skin cancers in immune suppressed organ transplant recipients.

Pending ongoing safety and efficacy in trials, the company expects to file SCENESSE® for marketing authorisation approval (MAA) for EPP in Europe by 2011.

The company's program, including the pilot NSV trial, is fully costed and funded to its first MAA.

Clinuvel expects that, should the pilot trial NSV prove successful, the company will further pursue NSV in a larger patient cohort. It is anticipated that results from the pilot trial will be known by Q2 2011.

- End -

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/scenesse.

SCENESSE® is a registered trademark of Clinuvel Pharmaceuticals Ltd.

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.

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).

Clinuvel's initial focus is to test SCENESSE® in four clinical indications currently being trialled:

Indication	Description	Clinical Trial Status
Erythropoietic Protoporphyria (EPP)	Absolute sun/UV intolerance	Phase III trial full results reported July 2010 Confirmatory Phase III trial approved August 2009
Actinic Keratosis (AK) and Squamous Cell Carcinoma (SCC) in Organ Transplant Recipients (OTRs)	Skin cancer in transplant patients	Phase II trial started October 2007
Polymorphic Light Eruption (PLE / PMLE)	Severe sun/UV poisoning	Phase III trial preliminary results reported December 2009
Nonsegmental Vitiligo (NSV)	Pigmentary disorder	Phase II pilot trial to commence in 2010

Phase I and II human clinical trials using SCENESSE® have demonstrated that the drug is well tolerated and no significant safety concerns have been identified to date. Following successful conclusion of the development program, Clinuvel will work closely with global regulators to facilitate marketing approval of SCENESSE®.

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

For more information contact:
Europe: Daniela Schaefer, Head of Business Operations Europe, Clinuvel AG T: +41 41 767 45 45
Australia: Clinuvel Pharmaceuticals Ltd Melbourne T: +61 3 9660 4900
E: investorrelations@clinuvel.com