Clinuvel Communiqué

JULY 2012

CONTENTS

CEO's Overview	1
Clinuvel representation at scientific and financial events	2
Swiss reimbursement underway for SCENESSE® (afamelanotide)	2
Phase III EPP (US) underway	2
Share price (ASX:CUV)	3
New video online – Liver transplantation in EPP	3

CEO'S OVERVIEW

I write at a time when the company is eagerly awaiting the first response from the European Medicines Agency (EMA) to its February filing of SCENESSE® (afamelanotide) for marketing authorisation (MAA). The process of obtaining this critical authorisation is regulated and dictated by the EMA's timelines. At fixed time points that are determined by the EMA, the Clinuvel team will be invited to respond to questions of the EMA reviewers. The EMA's scrutiny may also culminate in a face to face plenary meeting with the Committee for Medicinal Products for Human Use (CHMP) of the EMA. During this meeting, the company's representatives would be expected to provide an oral explanation of all aspects of the development and post-marketing for SCENESSE® to the panel of assessors.

Those who have invested in companies developing novel drugs will understand that the uncertainty at the start of the development program caused by a lengthy clinical and regulatory process gradually diminishes as the program progresses. These investors recognise that Clinuvel is indeed arriving at the final stage of review, an exciting phase concluding seven years of work.

FUNDRAISING AND MARKET SUPPORT

This week's key news is, of course, that sophisticated institutional investors have joined the company. This fresh injection of capital will enable the company to focus on concluding the Phase III EPP trials in the US and to advance the vitiligo program. The capital raised was issued at a notable premium above prevailing market price and serves as endorsement of management's strategy and recognition of the company's intrinsic value. I welcome those new shareholders and look forward to sharing our results and advancements with you.

For the second time during my tenure with Clinuvel, I decided last week to invest in the Company as a way of deepening my support and conviction in the chosen strategy. The purchase of A$100,000 of Clinuvel's ASX stock on market underpins my firm belief in the utility of SCENESSE® and the communities we serve.

EMA FILING UPDATE

Naturally, we wish to keep you up to date on our regulatory progress whilst at the same time being mindful of not wanting to fall foul of the EMA's strict prohibitions on disclosure to third parties.

Our main focus is on erythropoietic protoporphyria (EPP) because prophylactic treatment of this disease with SCENESSE® addresses an "unmet clinical need". Both regulatory and reimbursement agencies look with favor on such drugs. The ability to change patients' lives by offering a pharmaceutical treatment is acknowledged and much appreciated by the authorities. From a commercial perspective, value can only be created when the main regulators, the EMA and FDA are persuaded of the integrity and merits of a medical solution. Clinuvel is confident that it is fulfilling this criterion.

In addition to the EPP program it has become apparent that data from the other clinical applications – solar urticaria (SU), polymorphous light eruption (PLE), photodynamic therapy (PDT) and other photodermatoses – have served to demonstrate safety in multiple populations with varying underlying disorders. This safety data has been received well by both regulatory agencies thus far.

(Continued on page 2)

The approval process in the US is somewhat similar to that in Europe. We anticipate that the FDA will accept the dossier filed in Europe alongside additional data from the recently commenced confirmatory Phase III EPP study, CUV039, thereby providing the FDA with data generated on 'home-soil'.

US PROGRAMS: CUV102 VITILIGO STUDY AND CUV039 EPP STUDY

For Q3, our expectation is to be able to assess results from our vitiligo program beyond the clinical observations made to date. By then approximately 60 vitiligo patients – patients of darker complexion with a potent reservoir of follicular stem cells – will have completed this program of comparing, on the one hand, SCENESSE® acting in conjunction with narrowband UVB (NB-UVB) light therapy versus use of NB-UVB alone on the other hand.

Our program has attracted significant attention in the US due to the novelty of repigmenting patients in a disease which is considered largely unresponsive to any current therapy. These promising results should allow us to advance this program to Phase IIb.

In the US, a final Phase III trial in EPP is under way. We anticipate that all patients will be enrolled shortly, with the study expected to conclude by the end of December 2012 and data management and analysis to follow. In reiteration, Clinuvel's teams expect to file a New Drug Application (NDA) with the FDA in 2013.

The company is carefully managing and monitoring its financial situation to ensure that we will be able to guide the teams through the EMA procedure and scrutiny. At the same time, the distribution of SCENESSE® continues to be under close observation to preserve Clinuvel's capability as supplier of the drug to the EPP community.

Your continued support is now more essential than ever in enabling the CUV team to steer SCENESSE® past the chequered flag.

Philippe Wolgen

CLINUVEL REPRESENTATION AT SCIENTIFIC AND FINANCIAL EVENTS

RECENT:

- BioInvest Israel 2012 – Haifa (March 5-6)
- 70th Annual Meeting of the American Academy of Dermatology (AAD) – San Diego, USA (March 16-20)
- Bio Europe – Spring – Amsterdam (March 19-21)
- Euro-Biotech Partnering Summit – Paris (May 30-June 1)

UPCOMING:

- 17th European Society for Pigment Cell Research Meeting – Geneva (September 11-13)
- 21st European Academy of Dermatology and Venereology Congress – Prague (September 27-30)

SWISS REIMBURSEMENT UNDERWAY FOR SCENESSE® (AFAMELANOTIDE)

In April 2012 Clinuvel announced that SCENESSE® (afamelanotide) had been accepted for full reimbursement in Switzerland by two leading health insurers for the prophylactic treatment of erythropoietic protoporphyria (EPP), prior to the drug's formal approval by Swissmedic, Switzerland's regulatory authority. Since then other insurers followed and now a great number of Swiss EPP patients are able to obtain the drug. Patients are clearly benefiting from the supply and enthusiasm is high among the patient community.

Under a 2011 amendment of Swiss Law (Verordnung der Krankenversicherung, art. 71), health insurers have the option of recommending reimbursement of medicinal products for the treatment of severe or life-threatening diseases prior to their formal approval in Switzerland. SCENESSE's safety and clinical efficacy profile together with the lack of existing alternative treatments were decisive factors leading to this decision.

With the onset of summer in the Northern Hemisphere, the company has finalised this arrangement and EPP patients are now receiving SCENESSE® under the reimbursement scheme. This is an essential step in the introduction of the drug ahead of MAA in Europe.

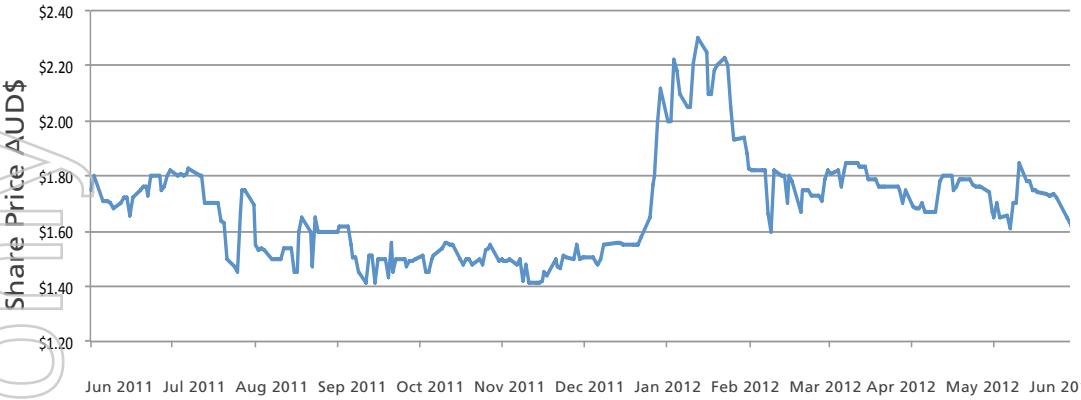
This year we hope to be able to file for registration of SCENESSE® in Switzerland as well, and the next country will be Australia.

PHASE III EPP (US) UNDERWAY

Clinuvel's confirmatory Phase III US study of SCENESSE® (afamelanotide) in erythropoietic protoporphyria (EPP) commenced in late May across seven specialist centres (Alabama, California, Michigan, New York, North Carolina, Texas and Utah). The six-month, randomised, multicentre, double-blind, placebo-controlled study (CUV039) will recruit up to 100 adult EPP patients, with treatment expected to complete before the end of 2012.

CUV039 is the first Phase III study of SCENESSE® in the US and it is anticipated to be the final study in the company's global program to evaluate SCENESSE® as the first prophylactic therapy for EPP. Results from the study are expected at the end of Q1 2013.

SHARE PRICE (ASX:CUV)



ASX: CUV Share Price

Average Daily Volume (Past 3 months, ASX): 8,483

Clinuvel will release its next quarterly financial report (Appendix 4C) before the end of July.

NEW VIDEO ONLINE – LIVER TRANSPLANTATION IN EPP

Erythropoietic protoporphyria (EPP) is a rare disease causing absolute intolerance of skin to light. In about 5% of EPP cases, patients also experience liver failure, requiring a life-saving liver transplant.

Florence, an immunology PhD, career scientist and EPP patient, underwent a liver transplant in 1989 following a liver failure due to her EPP. In early 2012 Florence shared her story on camera, discussing her transplantation in depth. You can view this video on Clinuvel's website at http://www.clinuvel.com/en/news/webcasts/liver-transplantation-in-erythropoietic-protoporphyria-epp

Clinuvel is very grateful to Florence for being able to share her story online.

To view all our videos, log on to Clinuvel's website: www.clinuvel.com/en/news/webcasts
To recieve announcements go to: www.clinuvel.com/en/investors/news-publications/announcements
To subscribe to email updates register here: www.clinuvel.com/en/investors/news-publications/subscribe

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 program 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