Clinuvel communique

INTRODUCTION

Clinuvel is arriving at a point many of our patients and investors have longed for: **first commercial treatment for EPP patients**.

Last month our European teams conducted a number of training and accreditation visits at European Hospitals. The purpose of these site visits was to instruct staff, management and clinical personnel on the regulatory requirements for following up with EPP patients in the longer term, as well as to train all involved on data collection, entry and management. Medical data protection is an essential topic where patients' data are required for regulatory analyses. While data is entered by hospital staff, the onus of protecting patients' data lies with Clinuvel, as the Marketing Authorisation Holder. Many professionals, independent bodies, and regulators are involved in the process while Clinuvel is expected to guarantee that patients' privacy is protected and the data is secure.

As part of the post-marketing Risk Management Plan for SCENESSE® (afamelanotide 16mg)[1], Clinuvel was obliged to establish a European EPP Disease Registry (EEDR) which acts as the central point for data collection and extraction before periodic analyses can take place. Here, a number of disciplines play a role and additional resources have had to be recruited. A central role is given to the newly appointed Qualified Person for Pharmacovigilance who is responsible for the obligatory submission of any safety reports concerning the supply of SCENESSE®. Any safety signal – "adverse event" – arising during the post authorisation safety study (PASS), whether related to SCENESSE® or not, will need to be documented and analysed. This can range from known and expected adverse drug reactions (the most common of which are now well documented), to something like the flu or even a cycling accident. It can be easily seen how the strict data management, and the obligation to analyse, has an impact on a company's operational structure. At Clinuvel all these processes and structural adjustments are captured under the term 'pharmacovigilance' and enable the safe and lifelong treatment of patients receiving SCENESSE®.

For those who have only recently been introduced to the company, we gradually progress from a clinical development-focused company into a commercially-focused entity. Some personnel are adopting new roles and new staff has joined our growing UK operations. Seamlessly integrating these professional roles into our current and evolving business structure is essential and not easy.

As I have noted before pharmacovigilance is becoming one of Clinuvel's core long-term strategic assets. The complex processes and systems that are implemented provide defenses against potential future competitors entering our market, while the controlled distribution of the product hands us a unique position in serving specialized medical centres and hospitals. Our full understanding and control of the novel pharmaceutical product aims to give patients years of pleasure and benefit, but most importantly places Clinuvel in the optimal position to serve patients during an era when calls for treatments grow louder.

FINANCIAL MANAGEMENT

In managing our cash position we have curtailed expenditures under the ever increasing regulatory demands on the company, and intentionally reduced other development activities to focus the entire company on the commercial preparation of SCENESSE® in Europe. While we had to bring on board new staff and contract with new third party service providers, including a second legally

required European manufacturer, we kept our cash flow under control throughout 2015 and Q1 2016.

In anticipation of the European distribution of SCENESSE®, and awaiting confirmation of reimbursement in key countries, we considered the need to raise further funds at minimum dilution. The latter is a regular theme in the Board's discussions. Last month's capital raising was successful in that the company saw the subscription of reputable and established institutions who all support the direction of the company. As an integral part of risk management, securing the financial support of larger family offices and institutions is key to longer term success. I thank all who participated in the recent capital raising for their long term confidence in the Board's and management's decisions to navigate the company through years of uncertain times and challenges.

MARKET ACCESS SCENESSE®

As the northern hemisphere enters spring the team is acutely aware of the demand from patients and physicians. In the coming weeks we expect to finalise the distribution program in the first EU expert centre and facilitate treatment under the PASS protocol. We are now in the position to finalise submissions with various local and national authorities to ensure compliance and, above all, patient safety.

Numerous processes take place at the periphery of our core activity. For example, those who follow us closely will note an increase in the volume of online listings for SCENESSE® in pharmaceutical databases online. We have also progressed a number of – admittedly lengthy – discussions with several reimbursement authorities, most recently where we participated in a workshop with England's National Institute for Health and Care Excellence (NICE). A final reimbursement pricing structure will soon be established, with a consistent, transparent approach across Europe.

In parallel, we continue to see demand for SCENESSE® through expanded access schemes. The Swiss program – where some EPP patients have been under continuous care for a decade – continues, with patients to be treated in line with the approved European label. Prior to full commercialisation in Italy, the extended 648/96 Special Access will further facilitate treatment for patients ensuring continuity of supply.

VITILIGO

While our immediate focus of resource and energy has been on the European EPP roll out, our vitiligo program continues to progress globally. We expect data from the revised protocol study in Singapore to be available for analysis later this year, and patient responses continue to suggest effectiveness. Meanwhile, the animal study in modelling a vitiligo treatment regimen for human use is well underway to meet the demands of global regulatory agencies. We continue to receive queries from vitiligo patients and physicians on an almost daily basis asking about progress, it is clear that there is a significant, unmet need in this patient group.

The team continues to execute on its global programs with such focus and dedication while adapting to the rapidly changing needs of the business. **In the coming weeks we expect this approach will provide the ultimate goal in drug development – first treatment of patients with an authorised medicinal product.**

Dr Philippe Wolgen

AFAMELANOTIDE: A REVIEW IN ERYTHROPOIETIC PROTOPORPHYRIA

Late March saw the publication of a new review of the SCENESSE® (afamelanotide 16mg) program in EPP patients in the *American Journal of Clinical Dermatology*. For more information, see:
Kim ES & Garnock-Jones KP (2016). Afamelanotide: A Review in Erythropoietic Protoporphyria. *J Clin Dermatol* 17(2):179-85. Abstract online: http://www.ncbi.nlm.nih.gov/pubmed/26979527.

PLACEMENT OF A$8.3M COMPLETED SUCCESSFULLY

In March Clinuvel announced it had successfully raised A$8.3m via a private placement ("Placement") to existing and new international institutional and professional investors. The Placement was made at a price of A$3.30 per share, representing an issue price equal to the closing price on 10th March and a 2.9% discount to the 10th March 10-day volume weighted average price.

The funds raised will enable Clinuvel to expand the European commercialisation program for its novel drug SCENESSE® (afamelanotide 16mg) for patients with EPP. For more information, please see the announcements page of our website.

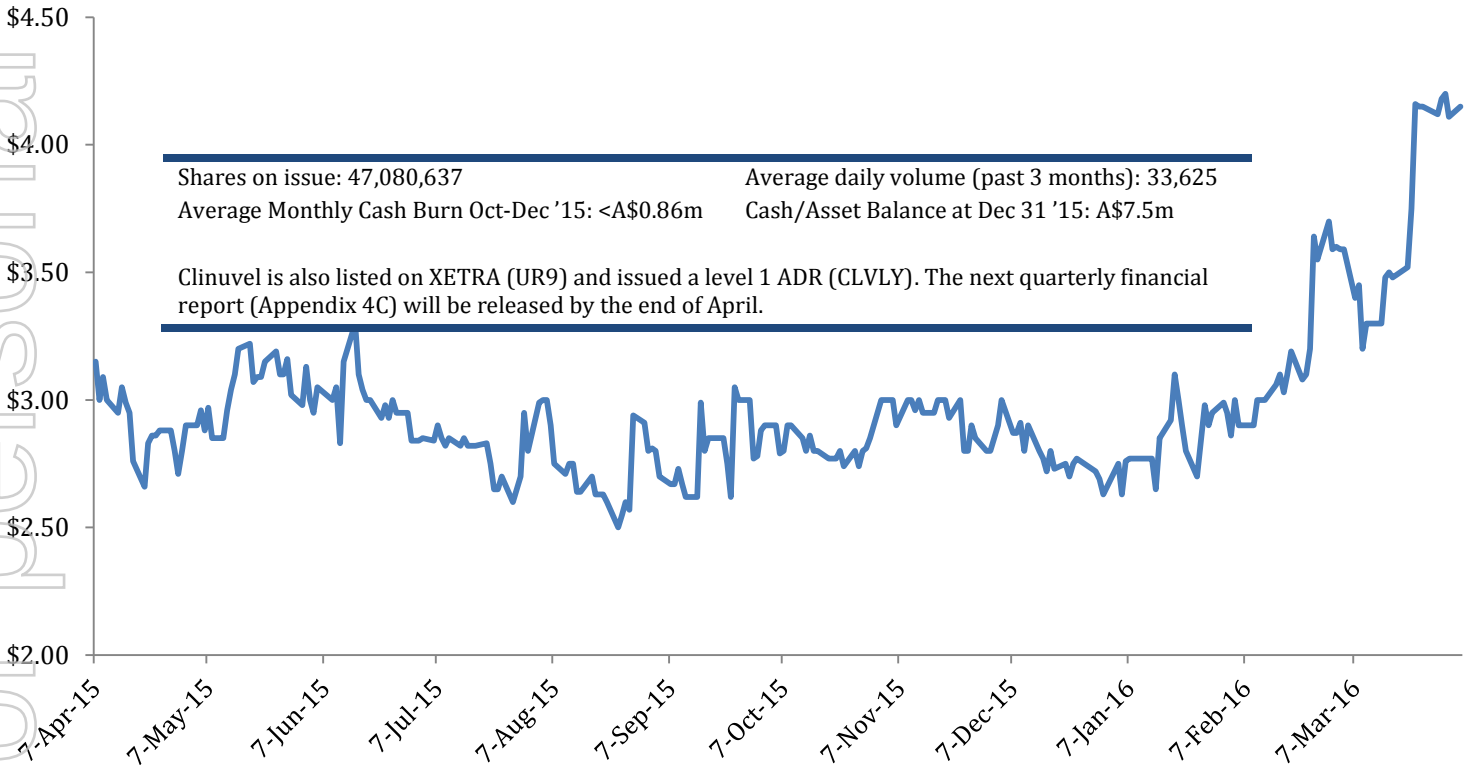
Recent Clinuvel representation

- International Congress on Porphyrins and Porphyrias – Dusseldorf (Sept 13-16)
- 24th EADV Congress – Copenhagen (Oct 7-11)
- British Porphyria Association Autumn Conference – London (Oct 24)
- Dutch EPP Patient Association Day – Arnhem (Nov 14)
- International Porphyria Patient Network Meeting – Rotterdam (Feb 6)
- American Academy of Dermatology 74th Annual Meeting – Washington DC (Mar 4-8)

Upcoming event

- 24th European Academy of Dermatology and Venereology Congress – Copenhagen (Oct 7-11)

ASX: CUV



Shares on issue: 47,080,637
Average daily volume (past 3 months): 33,625
Average Monthly Cash Burn Oct-Dec '15: <A$0.86m
Cash/Asset Balance at Dec 31 '15: A$7.5m

Clinuvel is also listed on XETRA (UR9) and issued a level 1 ADR (CLVLY). The next quarterly financial report (Appendix 4C) will be released by the end of April.

[1] SCENESSE® (afamelanotide 16mg) is approved in Europe as an orphan medicinal product for the prevention of phototoxicity in adult patients with EPP. Information on the product can be found on Clinuvel's website at www.clinuvel.com.