CLINUVEL

ASX ANNOUNCEMENT

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ASX: CUV | **Börse Frankfurt**: UR9 | **ADR Level 1**: CLVLY

CLINUVEL prioritises three strategic programs

First in series of operational changes to deliver milestones more efficiently, faster

EXECUTIVE SUMMARY

1. prioritising three core clinical programs
2. selection based on highest probability of clinical and commercial success:
    a. vitiligo
    b. adrenocorticotropic hormone (ACTH), and
    c. porphyrias (EPP and VP)
3. PhotoCosmetic development continues in preparation of market launches

CLINUVEL is today implementing one of several operational changes by prioritising its resources towards three key areas of clinical development: vitiligo, adrenocorticotropic hormone (ACTH) and the porphyrias (EPP and VP).[1] With this decision, the clinical programs in stroke, Parkinson's disease (PD) and xeroderma pigmentosum (XP) will be temporarily suspended and all internal resources deployed to the programs with the highest probabilities of, and fastest routes to, regulatory and commercial success.

Decision to strategically prioritise three key clinical programs

The Board of Directors has unanimously decided to redefine CLINUVEL's objectives based on new information while streamlining the current operations. On the basis of a range of factors and analyses, including new clinical guidelines in CNS disorders, chances of reimbursement, and the need to use internal resources more efficiently, the Company will focus on lead programs with highest need and largest market opportunity.

CLINUVEL's Board has also determined that a consolidation of the Group's activities will result in more RD&I[2] catalysts, which public markets will find easier to follow with progression along valuable milestones.

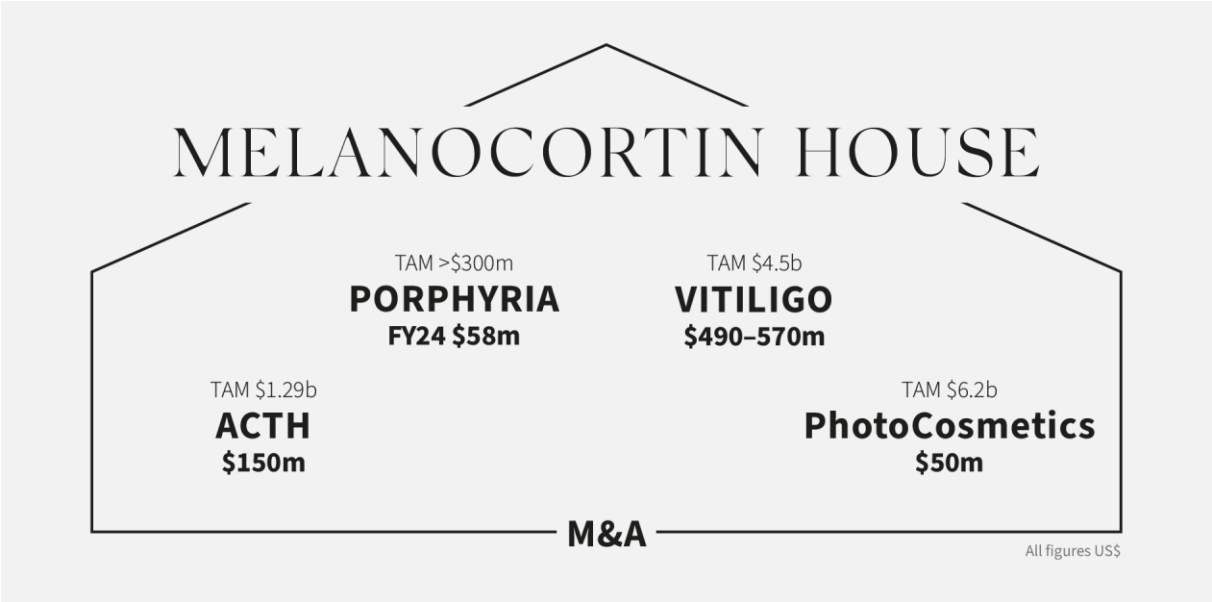
In addition to the three core clinical programs, CLINUVEL's non-pharmaceutical PhotoCosmetic product development continues, with the Company preparing launches of three product lines. CLINUVEL's existing team is being redeployed to maximise efficiency.

Commercial opportunities for melanocortins

CLINUVEL has established itself as a world leader in developing and commercialising melanocortins, peptides which play a key role in human physiology. The Company's first melanocortin technology – the novel drug SCENESSE® (afamelanotide 16mg) – has been established as the standard of care in porphyria (EPP)[3]. VP is one of the expansion programs where SCENESSE® assists patients in reaching a better quality of life. CLINUVEL completed a Phase II VP study during 2024 and is currently designing a late-stage confirmatory program for regulatory feedback.

Vitiligo affects 1-2% of the general population. It is generally anticipated that the vitiligo market will be divided between those companies offering localised transdermal products (creams, ointments) and those few companies who propose a medical solution for extensive disease of depigmentation by providing systemic (total body) treatment. CLINUVEL has established a clinical and regulatory pathway for SCENESSE® as a treatment for patients with ≥10% body surface area affected by vitiligo, with a Phase III clinical program ongoing.

The ACTH market opportunity attracts attention for a number of central nervous system disorders. CLINUVEL has announced it will initially focus on evaluating ACTH as a treatment for patients with infantile spasms , some other types of severe epilepsy in children, and multiple sclerosis, which are all disorders with a high unmet medical need. The Company is developing an instant release ACTH formulation as NEURACTHEL®, with manufacturing updates provided periodically.



CLINUVEL is establishing a house of melanocortins, addressing a range of unmet needs

Commentary

"This Board, with its newly appointed members, has deliberated extensively as to the short- and long-term objectives of the Company," CLINUVEL's Chair, Dr Jeffrey Rosenfeld said.

"By providing clear priorities we can accelerate development and generation of meaningful milestone news for public investors. Today's decision is the first of a number of far-reaching changes that we invoke," Dr Rosenfeld said.

"I personally witnessed the past five years within a large pharmaceutical conglomerate how considerable investments are easily abandoned to refocus clinical research teams on one or two sizeable opportunities," CLINUVEL's Director, Global Clinical Affairs, Dr Emilie Rodenburger said.

"From analyses of CLINUVEL the past months it has become clear that we need to rationalise, using our talent in three clinical areas with the highest chance of success. We must best use carefully accumulated resources to accelerate vitiligo, ACTH and porphyrias. At first sight, this may go against a market's expectation of more diversification, but we believe we have a sufficiently large portfolio with SCENESSE®, PRÉNUMBRA® (afamelanotide instant and modified release) and NEURACTHEL® (ACTH), which will be reinforced by today's decision.

"Our commitment to photomedicine remains strong, and we will continue to support those communities severely affected by light and UV through the Photomedicine Foundation and other initiatives globally," Dr Rodenburger concluded.

– END –

Footnotes

[1] Erythropoietic protoporphyria (EPP) and variegate porphyria (VP).

[2] Research, Development and Innovation.

[3] SCENESSE® is approved by the European Medicines Agency, US Food and Drug Administration, Australian Therapeutic Goods Administration and Israeli National Health Board for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP).

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL (ASX: CUV; ADR LEVEL 1: CLVLY; Börse Frankfurt: UR9) is a global specialty pharmaceutical group focused on developing and commercialising treatments for patients with genetic, metabolic, systemic, and life-threatening, acute disorders, as well as healthcare solutions for specialised populations. As pioneers in photomedicine and the family of melanocortin peptides, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for systemic photoprotection, repigmentation and acute or life-threatening conditions who lack alternatives.

CLINUVEL's lead therapy, SCENESSE® (afamelanotide 16mg), is approved for commercial distribution in Europe, the USA, Israel, and Australia as the world's first systemic photoprotective drug for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore, and the USA. For more information, please go to https://www.clinuvel.com.

Authorised for ASX release by the Board of Directors of CLINUVEL PHARMACEUTICALS LTD.

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Forward-Looking Statements

This release contains forward-looking statements, which reflect the current beliefs and expectations of CLINUVEL's management. Statements may involve a number of known and unknown risks that could cause our future results, performance, or achievements to differ significantly from those expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: our ability to develop and commercialise pharmaceutical products; the COVID-19 pandemic and/or other world, regional or national events affecting the supply chain for a protracted period of time, including our ability to develop, manufacture, market and sell biopharmaceutical products; competition for our products, especially SCENESSE® (afamelanotide 16mg), PRÉNUMBRA® or NEURACTHEL®; our ability to achieve expected safety and efficacy results in a timely manner through our innovative R&D efforts; the effectiveness of our patents and other protections for innovative products, particularly in view of national and regional variations in patent laws; our potential exposure to product liability claims to the extent not covered by insurance; increased government scrutiny in either Australia, the U.S., Europe, Israel, China and Japan of our agreements with third parties and suppliers; our exposure to currency fluctuations and restrictions as well as credit risks; the effects of reforms in healthcare regulation and pharmaceutical pricing and reimbursement; that the Company may incur unexpected delays in the outsourced manufacturing of SCENESSE®, PRÉNUMBRA® or NEURACTHEL® which may lead to it being unable to supply its commercial markets and/or clinical trial programs; any failures to comply with any government payment system (i.e. Medicare) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology and consumer based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; our ability to retain or attract key personnel and managerial talent; the impact of broader change within the pharmaceutical industry and related industries; potential changes to tax liabilities or legislation; environmental risks; and other factors that have been discussed in our 2024 Annual Report. Forward-looking statements speak only as of the date on which they are made, and the Company undertakes no obligation, outside of those required under applicable laws or relevant listing rules of the Australian Securities Exchange, to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. More information on preliminary and uncertain forecasts and estimates is available on request, whereby it is stated that past performance is not an indicator of future performance.

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