CLINUVEL

ASX ANNOUNCEMENT

CYACÊLLE
Polychromatic Solar Care – λ3

Melbourne, Australia, 1 March 2023	**ASX:**	CUV
	Börse Frankfurt:	UR9
	ADR Level 1:	CLVLY

A media release accompanying this announcement is available from CLINUVEL.com; please visit CLINUVELDNA.com, for in-depth information.

EXECUTIVE SUMMARY

- CLINUVEL launches CYACÊLLE, first dermatocosmetic product
- next generation polychromatic solar care (λ3)
- skin care for those at highest risk of photodamage, skin cancer(s)
- target populations:
  - immune-suppressed (IS)
  - skin cancer history (SC)
  - extreme outdoors (EO)
- first distribution: to patients with photo-induced skin disorders
- CYACÊLLE is an adjuvant non-prescription dermatocosmetic product, and does not substitute afamelanotide (Rx)

CLINUVEL today announced the launch of the first of four healthcare product lines with CYACÊLLE, a polychromatic screen, or next generation of solar care (λ3), formulated to protect skin against ultraviolet B (UVB), ultraviolet A (UVA), and high-energy visible (HEV) light. The Company successfully developed the world's first systemic photoprotective pharmaceutical, SCENESSE® (afamelanotide 16mg), treating patients intolerant to light due to the genetic disease erythropoietic protoporphyria (EPP). Consequently, CLINUVEL has been in the best position to translate its technological and clinical knowhow to non-prescription products for people at highest risk of light-induced skin damage.

CLINUVEL's MISSION – UNMET MEDICAL NEED

The objectives of the Company are to solve medical and healthcare problems for those who have remained unattended and unaddressed (unmet need).

The Group distinguishes itself by long-term follow up of its partners, suppliers, patients, and physicians, and now aims to continue a longitudinal approach to specialised populations.

As the first of four product lines, CYACÊLLE provides localised skin protection benefiting three distinct populations at highest risk of photodamage and skin cancer(s). These are individuals who are longer-term immune-suppressed (IS), affected by skin cancers (SC) either personally or within their immediate family, and those who spend extended time outdoors (EO), such as farmers, outdoor and construction workers, and professional athletes.

CLINUVEL's strong foundation remains pharmaceutical development of melanocortins (specialised hormones) in multiple formulations, while four non-prescription product lines are to benefit wider audiences. These consist of:

(i)	CYACÊLLE	– polychromatic care for extreme conditions
(ii)	reflective & refractive screens	– ultimate polychromatic screens
(iii)	melanocortin based emulsions	– assisted DNA repair
(iv)	melanocortin based emulsions/lotions	– stabilisation of skin pigmentation

CYACÊLLE - NEXT GENERATION SOLAR CARE (λ3)

The first product, CYACÊLLE, is a blend of active ingredients which have been shown to protect against UV and HEV radiation, providing polychromatic photoprotection. The smallest particles of light, photons, affect our skin during daily light exposure along the invisible (320-400 nanometres) and visible spectrum (400-650 nanometres).

The product will first be distributed through hospitals to patients suffering from EPP and XP[1], as an adjuvant (not substitution) to the systemic treatment provided by SCENESSE®, and in a second instance through a dedicated e-commerce platform, initially to European audiences (CLINUVELDNA.com).

COMMENTARY

"It is certainly not a trodden path for a pharmaceutical company to venture into specialised consumer markets, however we built technology and knowhow over decades, translating to products for people at highest risk of photoageing and skin cancers," CLINUVEL's Chief Scientific Officer, Dr Dennis Wright said. *"We arrived at CYACÊLLE, protecting against a much broader range of ambient wavelengths, and therefore providing for specialised skin care under extreme conditions.*

"We see much upside in diversifying the Company a stone's throw away from our focus on clinical medicine, to areas where we find similar health issues from solar and environmental risks. In pursuing a broader mission, we anticipate that our dermatocosmetic product lines will attract new audiences."

"Why would we not take the opportunity of addressing skin issues, affecting 33% of the general population," CLINUVEL's lead Formulation Scientist, Jelly Barrera said. *"We are establishing a dialogue with those people who care most about photodamage, repair of damaged DNA, and skin cancer risks. As a clinical leader and pioneer in our field, I strongly feel it is our duty to do more with that specialised clinical knowledge. In reaching millions of people affected by photoageing and skin damage, I am part of a pharmaceutical team that refreshingly dares to expand its vision to healthcare issues affecting most of us."*

– END –

[1] Xeroderma pigmentosum, a genetic disorder leading to frequent and lethal skin cancers

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 the general population. 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, DNA repair, 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 2022 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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