CLINUVEL

ASX ANNOUNCEMENT

# Commercial Update SCENESSE®

*EVALUATION CALENDAR YEAR 2022*

| | | |
|---|---|---|
| **Melbourne, Australia, 9 March 2023** | ASX: | CUV |
| | Börse Frankfurt: | UR9 |
| | ADR Level 1: | CLVLY |

## Executive summary

**USA**

- US Specialty Center network expanded (+17% - CY2022)
- Target network of up to 120 US Specialty Centers
- Increased demand (+27% - CY2022)
- Medicare, Medicaid, VA, TRICARE patient access
- US Savings Program active (15% uptake)

**Europe**

- Increased prescriptions (+15% - CY2022)
- Highest number of patients treated to date
- Uniform price maintained, access discussions ongoing
- Scotland accepts SCENESSE®, England stalls market access

CLINUVEL today published its 2022 status report on the commercial distribution of SCENESSE® (afamelanotide) in the United States and Europe. The therapy is prescribed as a systemic photoprotective to adult patients diagnosed with erythropoietic protoporphyria (EPP).

Since first introduction in June 2016, the number of patients, prescriptions, and centres have grown year on year.

## US DISTRIBUTION

SCENESSE® is prescribed in 28 states, and directly supplied to trained and accredited hospitals and medical offices. The Company's initial intention had been to engage 30 Specialty Centers. However, as therapy demand increased, the network of prescribers was expanded to more than 50, with a 17% increase in 2022. Treatment demand rose by 27%, and prescriptions by 32%.

The US team is currently focused on accrediting up to 120 US Specialty Centres, both for the treatment of EPP patients, and as an introduction of the treatment option for vitiligo patients.

## US REIMBURSEMENT

SCENESSE® is the first systemic photoprotective therapy introduced to the US healthcare system. Therefore an application was filed for the incorporation of a new J-code in 2022. Following approval of the J-code, a high number of health insurers have included coverage of SCENESSE® in insurance formularies, drug policies, and hospital listings, enabling faster and more efficient approval by Prior Authorization (PA). Over 100 US insurers are covering the annual treatment cost of SCENESSE®.

In 2020, the 'SCENESSE® Savings Program' was launched for eligible patients to reduce insurance costs. Approximately 15% of commercially insured beneficiaries participate in the Program, with highly positive feedback.

CLINUVEL is establishing government healthcare programs with the Centers for Medicare & Medicaid Services (CMS) and negotiating terms with the Veterans Affairs (VA) Department. Recently, the first patients covered by Medicare and Medicaid have gained treatment access. Final negotiations are taking place to reach agreement with VA/TRICARE to ensure entitled patients receive SCENESSE®. The overall mission is to make treatment accessible to all US EPP patients in need, accommodating the various categories of healthcare coverage.

## EUROPEAN PATIENT TREATMENT

European treatment access expanded throughout 2022, with more patients receiving drug than any previous year, and a 15% rise in prescriptions.

Since the launch of SCENESSE®, a regional uniform pricing policy was maintained, treating all payors equally and transparently. Progress was made with a number of regional and national payors, with expectations that final negotiations will lead to further therapy access. In January 2022, a second agreement was reached with the German National Association of Statutory Health Insurance Funds (GKV-Spitzenverband or GKV-SV).

The European Medicines Agency (EMA) continues to review an application to expand the SCENESSE® label to adolescent EPP patients (aged 12-17). A final EMA decision is expected in the first half of 2023.

## UK REIMBURSEMENT

In Scotland SCENESSE® is being prescribed as standard of care to EPP patients under equivalent commercial terms to those in the European Economic Area.

In contrast, England's National Institute of Health and Care Excellence (NICE) has, to date, failed to make the treatment available for English EPP patients, in spite of the findings and appeal grounds upheld by NICE's independent Appeal Panel. This Panel had concluded that its Highly Specialised Technology Committee – in its decision to deny treatment to EPP patients – had failed to take into account anti-discrimination legislation, and that the Committee had unjustly assessed the treatment effect of afamelanotide.

## COMMENTARY

*"I can be very proud of my team's work to broaden US access to SCENESSE®,"* CLINUVEL's Director of North American Operations, Dr Linda Teng said. *"We set out to consider patients' needs, location and insurance status, thereby establishing a dedicated network of Specialty Centers. We have seen a year-on-year increase in*

*treatment demand. This year we have set new and high challenges, and we will rise to meet these."*

*"This business continues to require a detailed yet different approach to two continents, such that treatment arrives at the right location and on time,"* CLINUVEL's Director of Global Operations, Mr Lachlan Hay said. *"Unexpectedly, our distribution and market access approaches now serve as models to other companies wishing to enter markets with new pharmaceutical products. Our immediate task is to evaluate, evolve, become more efficient, and expand the Group.*

*"In spite of Prime Minister Sunak's recent comments on the nation spearheading to attract pharmaceutical innovation, the reality is that NICE appears to be an agency without much political oversight.*

*"For now, we can only conclude that NICE has demonstrated a systematic approach to frustrate English EPP patients' access to the only available therapy. From close up it is an opaque organisation, squandering its administrative powers, as its own Appeal Panel had uncovered. We await their further documentation but remain focussed to enable treatment for English EPP patients,"* Mr Hay said.

**– END –**

**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.

SCENESSE®, PRÉNUMBRA®, and NEURACTHEL® are registered trademarks of CLINUVEL.

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

**Media Enquiries**
Monsoon Communications
Mr Rudi Michelson, 61 411 402 737, rudim@monsoon.com.au

**Head of Investor Relations**
Mr Malcolm Bull, CLINUVEL PHARMACEUTICALS LTD

**Investor Enquiries**
https://www.clinuvel.com/investors/contact-us

**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.

www.clinuvel.com

Level 11, 535 Bourke Street, Melbourne, Victoria, Australia, 3000, T +61 3 9660 4900, F +61 3 9660