CLINUVEL

News Communiqué II, 20 March 2024

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

Fellow Shareholders,

American Academy of Dermatology (AAD)

When we look back at the AAD Meeting and its satellites, held in San Diego from 7-12 March and visited by more than 20,000 delegates, a number of sessions jump out. First is the plenary keynote lecture given by Professor Henry Lim, a knowledgeable and acclaimed academic in clinical dermatology and research. His lecture on new developments in photodermatology included numerous mentioning of SCENESSE® (afamelanotide) as a breakthrough drug in erythropoietic protoporphyria (EPP) and, prospectively vitiligo. Equally impressive were the plenary presentations given by Professor Lesley Rhodes and Dr Pearl Grimes, both referencing SCENESSE® as a drug for the future in vitiligo and photodermatoses, UV-provoked disorders.

Clinical attention for SCENESSE® is increasing year on year, thereby keeping in mind that its longer=term safety profile has assisted in gaining overall acceptance among US medical specialists.

The team was most encouraged to see a new case study presented to the AAD from our vitiligo program, with the patient visibly responding well to treatment with a marked effect on quality of life. I encourage all who are interested in the program to review the release following the AAD.

Los Angeles First Event

We equally revisit the first US event held on 29 February at the home of Ms Stefani Germanotta – known to many as gifted artist Lady Gaga. After two years of preparation, we believed the moment was right to bring CLINUVEL to the attention of broader influential audiences. The attendees were a mix of Silicon Valley investors, captains of industry, entrepreneurs, and prominent individuals from the entertainment sector. Sean Parker – known for his tenure as first president of Facebook, founder of Napster and Board member of Spotify, and foremost co-founder of the Parker Institute for Cancer Immunotherapy – led a panel discussion together with Ms Germanotta on CLINUVEL's future and drug candidates. Michael Polansky, the long-standing partner of Ms Germanotta had introduced the differentiated business model adopted, and the value proposition since turnaround in 2005. Questions were received from the audience on the availability of SCENESSE® in the US, the future of PhotoCosmetics, and the geographical headquarters of the Company. Prominent physicians in attendance spoke about photomedicine and vitiligo. Overall, the reception was much better than expected from an audience mostly unfamiliar with CLINUVEL's melanocortin focus. Following evaluation, we will further update our shareholders on a second event to be organised on the US West Coast.

Share Buy-Back

Long-term financial management since 2005 resulted in preservation of funds for future needs and challenges. We have now reached one such point in support of shareholders through a first share buy-back.

More than ever, we will continue a strategy to look after our funds; it is precisely due to consistent financial management – an approach distinguishing CLINUVEL from others, and which has delivered minimal dilution – that we are in the enviable position to deploy cash for a buy-back program; we wish to ensure that CLINUVEL's shareholders are seeing appropriate valuation.

We have chosen the moment of a repurchase as first clinical results for 2024 are published, and we will keep at it until those who gamble against the Company have understood the message. Given the expected future cash flows, we are in the position to prolong the program when required, since Board

and management do not believe that market value has reflected the Company's performance in recent months.

To those shareholders who have proven supportive, we have waited for the right moment to strike on your behalf. To those individuals who continue to disseminate false, misleading and negative information online, we will not shy away from other measures since that behaviour provides welcome ammunition to those wanting to see a lower valuation.

The share buy-back further increases the relative percentage of ownership for our owners, and thereby compounds CLINUVEL's strategy to minimise dilution. With 1,500,000 shares (or approximately 3% of the outstanding share capital) to be repurchased, we hold a longer-term view on capital management without jeopardising p plans to reinvest and expand the Company.

The first trading days after the buy-back announcement on 14 March dispelled the myth that the share price is reflective of performance only, as had been shown in recent years. We will continue to act according to the best interests of the business long-term.

Executive Management

Since the Company has matured and is entering larger markets, all executives carry responsibility for essential parts of the operations and are expected to fulfill a public role, which we wish to see increased.

We adhere to a matrix structure, whereby executive managers are accountable for specialties within our business. The current executive team counts nine, but will be expanded by minimum two in the next few months. The current executive team, with a median of 16 years of service, has helped shape the function and focus of the business to ensure we can meet the objectives set.

Based in Australia, Dr Dennis Wright and Darren Keamy have been core to the Company's direction for nearly two decades in the roles of Chief Scientific Officer and Chief Financial Officer/Company Secretary.

A pharmacist with a PhD in xenobiotic metabolism, Dr Wright has a pharmaceutical career spanning more than 40 years with Nicholas Kiwi, Faulding/Mayne, CSL and CLINUVEL. During this time, he worked across basic and clinical research, regulatory affairs, pharmacovigilance, business development, in-licensing, and marketing. It is from this diverse background that he has led CLINUVEL's late-stage clinical development program for EPP as well as steering successful regulatory filings for SCENESSE® in Europe, the USA, Australia, and Israel. His role has extended in recent years to facilitate new clinical programs for afamelanotide as well as overseeing new product development and scientific affairs.

In his dual role, Mr Keamy ensures financial discipline while maintaining a strong focus on governance and compliance. From early in his time with CLINUVEL, Mr Keamy was responsible for maintaining strict controls to enable the Company to achieve profitability and reinvest in long-term growth. As the business has evolved, Mr Keamy has overseen the addition of new entities and structures to both enable commercial sales as well as maintain tax efficiencies. Mr Keamy provides counsel to the Board across his role as well as maintaining corporate governance structures for the Group and leading global compliance. A qualified CPA, Mr Keamy previously held roles with global packaging specialists Amcor in Australia, as well as Salomon Smith Barney (now part of Citigroup) and Superdrug Stores in the UK.

Joining CLINUVEL's Melbourne office five years ago, Malcolm Bull initially built out the Company's IR program with a focus on analyst and Australian institutional engagement. Recognising the need for greater operational support in Australia amidst the COVID-19 pandemic, Mr Bull's role with CLINUVEL evolved in 2021 to the remit of Head of Australian Operations and Investor Relations. Previously an economist within the Australian Federal Government and private sector, Mr Bull then spent more than two decades in banking across credit, business development and strategy, and private wealth management, working with Commonwealth Bank of Australia, Bank of Western Australia, National Australia Bank, and ANZ. This included time in general management for ANZ in the Philippines and as part of the Victorian state management team for CBA Corporate. Mr Bull has managed to attract six sell-side analysts since his arrival.

Head of North American Operations Dr Linda Teng, qualified as a PhD pharmacist, has established the Company's commercial presence, building a network of Specialty Centers and commercial programs enabling EPP patients to receive treatment in both the USA and Canada. With a background in clinical pharmacy and clinical pharmaceutical development – at BioMarin and for more than 16 years at CLINUVEL – Dr Teng also heads the vitiligo program in North America. The US team has grown quickly over the past 18 months to incorporate new functions, including patient support and in-house counsel, adding complexity but greater bandwidth to the operations under Dr Teng's purview.

Director of Global Operations Lachlan Hay, qualified with a Masters in International Relations, supports the executive and senior management teams as well as maintaining responsibility for the delivery of key business objectives. Having joined the business in a corporate communications role in Australia, Mr Hay then assumed roles in Europe and Asia. He was the first General Manager of the UK business, overseeing the introduction of SCENESSE® into European markets since 2016, and assumed a broader operational position in response to the needs of the business.

CLINUVEL's largest team reports into its European entities, with four of the executive responsible for various tasks: VP, Commercial Affairs Antonella Colucci, Senior VP Regulatory Affairs Dr Rose Quadbeck-Diel, Head of Quality and Drug Safety Dr Azza Hamila, and me as Managing Director.

Mrs Colucci has been responsible for commercial matters ex-North America since early access programs for SCENESSE®, while working closely with the US team to ensure continuity of business. Having spent many years working within the medical industry in Italy, Mrs Colucci was instrumental in the expansion of CLINUVEL's Italian 648/96 program and subsequent Swiss special access scheme. These two programs – which facilitated subsidised reimbursement of the drug prior to its marketing authorisation – provided CLINUVEL with commercial proof-of-concept for SCENESSE® and laid the foundations for Mrs Colucci to lead the Company's successful commercial activities since 2016. With responsibilities across pricing, compliance, and distribution, Mrs Colucci is currently focused on expanding the Company's commercial reach in both new and existing regions.

Having spent over 30 years in global regulatory affairs and quality assurance in large and mid-sized pharmaceutical entities in Germany and Switzerland – including Baxter Oncology, Asta Medica, and Mundipharma – Dr Quadbeck-Diel ensures CLINUVEL is compliant with, and able to adapt to, a changing regulatory landscape. A PhD biochemist, Dr Quadbeck-Diel's time with CLINUVEL has included navigating marketing authorisation filings and compliance, shaping the Company's Brexit response, and implementing new European regulatory initiatives such as the falsified medicines regulations. In recent years Dr Quadbeck-Diel has worked to expand CLINUVEL's regulatory team to prepare long-term regulatory projects and new marketing filings.

Dr Hamila has played a central role in CLINUVEL's commercial scale up, establishing new internal standards in GxP, with a focus on manufacturing, distribution, and pharmacovigilance. Her work has enabled the Company to achieve long-standing compliance, giving authorities comfort that CLINUVEL conforms to strict international regulations and can maintain the licenses necessary to perform critical manufacturing and distribution functions in-house. Dr Hamila's position encompasses both Responsible Person and Qualified Person roles in various jurisdictions within the quality management system, as well as being responsible for supplier management and patient safety. A pharmacist, Dr Hamila has previously held quality assurance roles with Orphan Europe (Recordati), Sanofi Aventis, and Roche before joining CLINUVEL's UK team.

Summary: CLINUVEL's Executive Team

Malcolm Bull
Head of Australian Operations and Investor Relations, Australia

Antonella Colucci
VP, Commercial Affairs, Switzerland

Dr Azza Hamila
Head of Quality Assurance and Drug Safety, UK

Lachlan Hay
Director of Global Operations, Singapore

Darren Keamy
CFO & Company Secretary, Australia

Dr Rose Quadbeck-Diel
Snr VP Regulatory Affairs, Switzerland

Dr Linda Teng
Director of North American Operations, USA

Dr Dennis Wright
Chief Scientific Officer, Australia

Dr Philippe Wolgen
Managing Director, Monaco

Investor Relations, Communications

Investor Relations Activities to 30 June 2024

Key features of the IR program for the remainder of financial year 2024 are:

- 25-28 March — Non-Deal Roadshow (NDR), Germany.
- 27 March — Düsseldorf Investor Briefing.
- Mid-April — Virtual NDR, USA.
- 1 May — Capital Markets Briefing, Sydney.
- Mid-May — NDR, Singapore and Hong Kong.
- 23 May — Wilsons Rapid Insights Conference, Melbourne.
- June — Jefferies Conference (tbc) and NDR USA.

This program ensures CLINUVEL's story continues to be told to multiple investor audiences. Central to this narrative are the objectives outlined at the 2023 AGM, which are being met:

Individual objectives CY2024	
1	SCENESSE® adolescent outcome EMA
2	SCENESSE® Canada Health submission
3	Vitiligo CUV105 completion recruitment
4	Vitiligo CUV107 start recruitment
5	XP-DNA Repair CUV151 read out complete (selected markers)
6	CUV156 read out complete (selected markers)
7	CUV154 start
8 ✓	Paediatric PK study CUV052 start – March 2024
9 ✓	VP CUV040 complete results – March 2024
10	CNS CUV803 completed with final results
11	CNS and or New Indication
12	NEURACTHEL® manufacturing progress
13	Website launch
14	PhotoCosmetics E-shop launched
15	CYACÊLLE global launch
16 ✓	Financial growth earnings: half year (Feb 2024), final year end

Financial Results - Half Year to 31 December 2023

The financial results of the Company in the six months to 31 December 2023 were announced on 22 February 2024. Compared to the six months to 31 December 2022, revenues grew by 10% and profit before tax was up 1.4% with a 28% rise in expenses to support the growth initiatives of the Company. Net cashflow provided by operating activities increased by 25.5% to $26.4 million. Assets increased by 9% to $211.7 million with the largest asset category, cash reserves, accounting for a high proportion (82%) of assets, rising by 11.2% to $174.5 million.

Expenses reflect our 2021 projections of $175 million invested over five financial years, for the remaining 18 months we are right on track to spend a further $60 million towards research, development and commercial activities. Research and development expenses continue to account for

around 40% of our total expenses. Investors are encouraged to review the webinar which accompanied the results release.

Photoprotection in Variegate Porphyria

One of the Company's milestones for CY24 was to deliver results from the first ever clinical study of a treatment for variegate porphyria (VP). In short, we observed that SCENESSE® provides photoprotection and clinical benefit in VP, with the primary CGIC measure showing a positive change – improvement up to three times baseline scores – in disease severity after treatment and improvements in clinical and quality of life measures. Full results can be accessed here.

It is satisfying to be able to announce positive results, not least for patients who lack any therapies and the dedicated physicians who facilitate clinical care. The study – conducted over spring and summer months in 2023 at two European clinical centres – provided key learnings which our teams must now consider and incorporate into future work.

Adolescent EPP Study Enrols First Patients

A second milestone has been met in recent weeks with the first patients treated in the CUV052 study. Generating pharmacokinetic data on the use of SCENESSE® in adolescent patients (12-17 years), this short protocol will enrol up to 28 patients (14 adolescents and 14 adults) across three European EPP Expert Centres. Results are expected later this year.

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Building a successful business on melanocortins is a rare privilege, whereby patients and families benefit at the end from long development cycles. Many shareholders hold out for the long run, decades of patience, others are driven by short-term expectations. For those who wish to see a house of melanocortins aggregating different therapies under one roof, patience is required. The next large market looming is vitiligo, and the EPP opportunity the past years enabled us to bridge and execute this program.

We wish you wisdom and patience in your allocation decisions.

Philippe Wolgen

– 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 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, assisted 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.

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 2023 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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