

CLINUVEL: 15 YEARS OF FOCUSED STRATEGY

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Malcolm Bull
Head of Investor Relations
CLINUVEL Group

CLINUVEL PHARMACEUTICALS LTD
ASX: CUV
Nasdaq Int'l: CLVLY
XETRA-DAX: UR9



CLINUVEL has spent more than 15 years focused on the development of an innovative product for a group of patients with an identified unmet medical need.

The Company has commercialized its first product, SCENESSE® (afamelanotide), in the USA and Europe.

The same consistent approach and strategy is now being taken to expand CLINUVEL to address further unmet needs and deliver new products.

LEGAL NOTICE

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 affecting the supply chain for a protracted period of time, including our ability to develop, manufacture, market, distribute and sell biopharmaceutical products; competition for our products, especially SCENESSE® (afamelanotide 16mg); our ability to achieve expected safety and efficacy results 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, 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® 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 based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; any failure 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; risks of viral infections, pandemics and slowdown of the supply chain; and other factors that have been discussed in our 2019 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 the forecasts is available on request. Past performance is not an indicator of future performance.

Your attention is drawn to our legal notice which we provide at the start of every presentation.

Strategy Designed with Purpose

- 2005: Reset strategy to specialize in treatments for unmet needs of rare genetic indications
- 2005-2019: Strategy executed with confidence
 - Stable, tenacious management, aligned with Board
 - World's first systemic photoprotective drug
 - Built profitable commercial operations
- 2020+: Evolving into a diversified, integrated pharmaceutical company providing treatments for multiple indications
 - Product development pipeline to progress
 - Key functions 'in-house'

CLINUVEL Profile:

- Established: 1999
- ASX Listed (CUV): 2001
- Nasdaq Int'l, ADR Level 1 (CLVLY): 2004
- Frankfurt Xetra-DAX (UR9): 2004
- HQ: Melbourne, Australia
- Operations: Europe, Singapore, USA and (pending) China



Today, CLINUVEL is a profitable, cash flow positive pharmaceutical business with a clear ambition to develop and deliver new products. The Company plans to evolve into a diversified pharmaceutical business providing treatments to multiple patient groups.

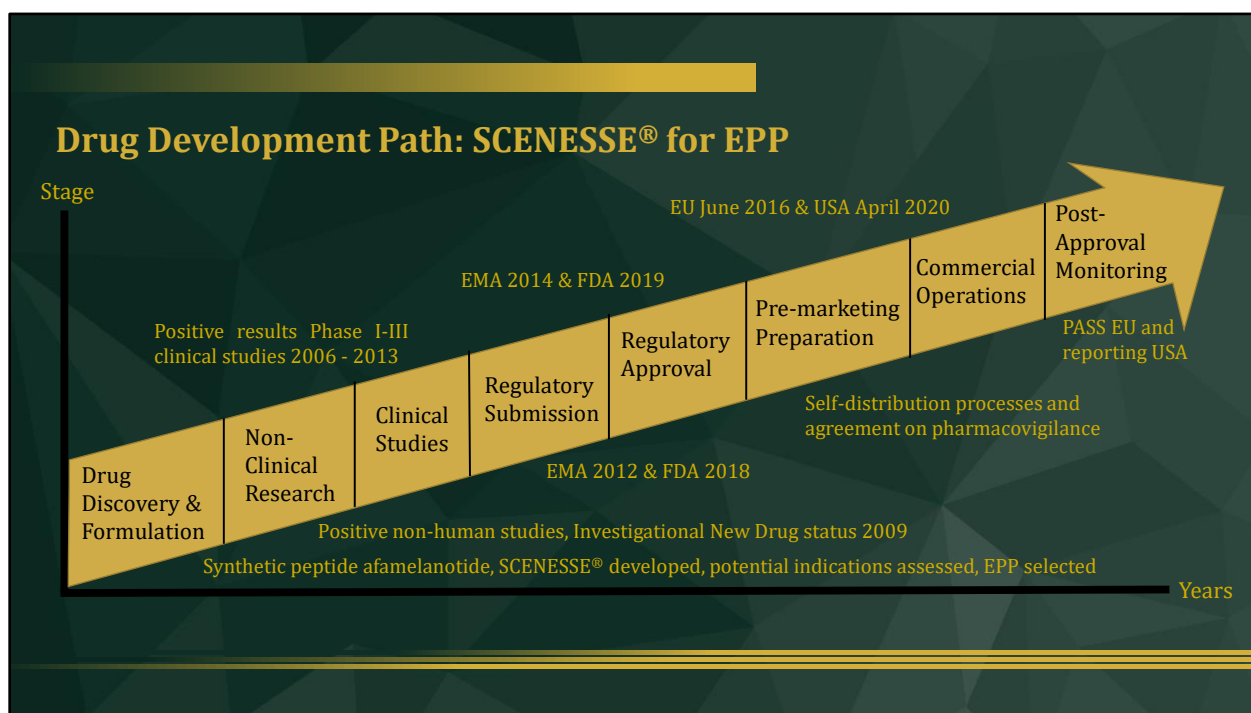
All this is the result of a strategy started 15 years ago by the same senior management team that is in place today, and has been implemented by a lean, consistent and tenacious team.

A new management team started in November 2005. Management redefined the business strategy to build a specialty pharmaceutical providing solutions for patients with genetic and dermatological disorders who lacked alternatives.

During the implementation of this strategy from 2005 to 2019, the CLINUVEL team evolved into experts in photoprotection and repigmentation of the skin, melanocortins (the family of molecules of afamelanotide) and related disciplines. They self-managed many aspects of strategy execution, including drug development, clinical studies, capital raisings, regulatory liaison, product distribution, and pharmacovigilance. It is rare in pharmaceuticals to undertake all these activities.

During this time we expanded our global presence with operations in Australia, Europe, Singapore, the USA, and soon, China.

Strategy needs to evolve. Having established a viable business we will continue to expand into new regions. We are progressing our product development pipeline to underpin our evolution into a diversified and integrated pharmaceutical company with key functions undertaken 'in-house', providing treatments for multiple patient groups and products for consumers.



The story of CLINUVEL's progression along the drug development path over the last 15 years provides insight to the implementation of the strategy from 2005:

- SCENESSE® was developed, arriving at an optimal formulation and dose for target indications.
- Several indications involving the interaction of light/UV and skin were assessed; erythropoietic protoporphyria (EPP) was selected as the initial indication.
- Non-clinical and clinical studies of SCENESSE® were conducted, focused on EPP.
- Regulatory approvals were achieved in the EU (2014) and USA (2019).
- Commercialization of world's first systemic photoprotective drug commenced in Europe (2016) and, since April 2020, in the USA.

Five clinical studies were conducted for EPP between 2006 and 2013 involving 352 participants. Two Phase III studies achieved statistically significant primary endpoints of increased exposure to light without phototoxicity, and improved patient quality of life. These results were a key part of regulatory submissions and were published in the *New England Journal of Medicine* and 12 other journals.

Given the conversion rate of new pharmaceutical drugs, particularly orphan drugs involving a new molecular entity, and the rare and unknown nature of EPP, the achievement of our scientific and regulatory team for effective direct liaison with the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) illustrates the persistence and tenacity of the CLINUVEL team.

As the product was commercialized in Europe, we also liaised with the FDA on the SCENESSE® dossier, gaining marketing authorization in October 2019.

Prior to commencing commercial operations in Europe in June 2016, a rigorous pharmacovigilance program, involving life-long follow up of patients, was agreed with the EMA.

Agreements in Europe have been necessary with payors on a country by country basis for reimbursement of the cost of treatment of SCENESSE®. Some negotiations are still ongoing.

We have recently commenced commercial operations in the USA, within six months of FDA approval.

Approved Indication: Erythropoietic protoporphyria (EPP)

- Lifelong metabolic genetic disorder
 - FECH deficiency 18q21 in the heme biosynthesis pathway
- Intolerance to light
 - (blue/green/UV, peaking at 408nm)
- Phototoxicity – painful anaphylactoid reactions and 2nd degree burns
- Causes social isolation, anxiety and fear
- Rare disorder, not well characterized
 - Prevalence 10,000 worldwide
- One approved treatment therapy



Phototoxic reactions in EPP patients.
Top image courtesy of the KE family.
Bottom image courtesy of the patient.



This and the next slide provide some facts about our approved indication and our approved treatment.

EPP is a poorly characterized rare (orphan) metabolic disorder. Due to a genetic defect, EPP patients are intolerant of visible light, meaning they must avoid all light/sun exposure or risk debilitating acute phototoxic reactions (anaphylactoid reactions and second-degree burns). Reactions may occur after just a few minutes of exposure of skin to light/sun and can last days to weeks.

SCENESSE® is approved to treat adult patients with EPP. The drug provides photoprotection to prevent phototoxic reactions (anaphylactoid reactions and burns).

There was no approved treatment therapy for EPP prior to the approval of SCENESSE® and we are proud to have filled an unmet medical need to make a difference to the lives of EPP patients.

SCENESSE® is the world's first systemic photoprotective drug.

Approved Treatment: SCENESSE® (afamelanotide 16mg)

- World's first systemic photoprotective drug
- New Molecular Entity, afamelanotide, activates melanogenesis, provides photoprotection
- Patent protected to late 2020s / early 2030s
- Regulatory approval confers marketing exclusivity – 10 years EU, 7 years USA
- Controlled distribution to accredited expert centers
- Injectable, controlled-release implant, every 60 days
- Rigorous pharmacovigilance program
- Long-term safety data
 - Over 9,800 doses; 95% patient treatment continuation



The development of SCENESSE® was completed after years of optimization of its formulation and appropriate dosage.

A controlled release injectable implant dose contains 16mg of the active ingredient, afamelanotide, a new molecular entity that induces melanogenesis and provides photoprotection.

CLINUVEL distributes SCENESSE® directly to trained and accredited expert and specialty centers in the EU and USA.

The product has maintained a positive safety profile based on:

- an increasing dossier, including real world data, of over 9,800 doses; and
- 95% patient treatment continuation year on year in Europe (post-authorization).

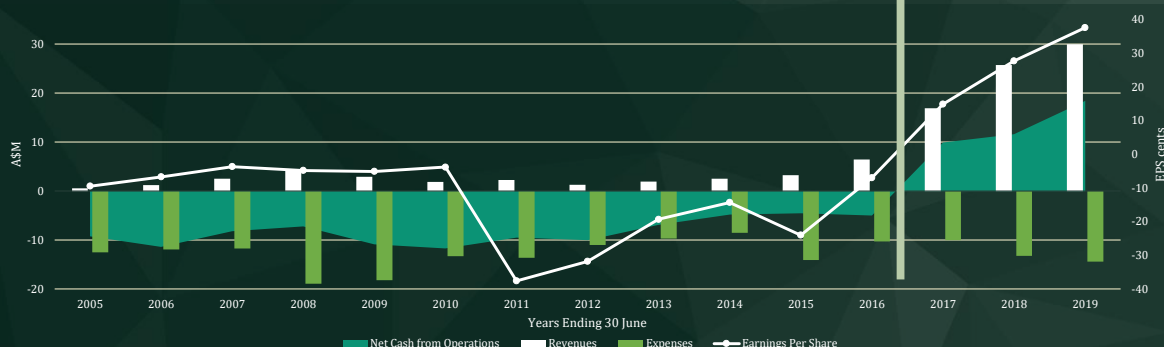
Financial Dynamics

R&D: 2005-2016

- cost-management
- self-arranged equity financing
- never below critical cash
- financial proof of principle 2010
- R&D cost SCENESSE®, A\$154m

COMMERCIAL: From 2017

- cost-management
- cash positive
- profitable
- debt-free
- dividend FY18 & FY19



Note: CUV continues quarterly reporting of cash flows; these reflect seasonal fluctuations due to cyclical treatment demand

CLINUVEL's financial performance over time has progressed through the Research & Development Phase into the Commercial Phase. All figures are reported in Australian dollars (A\$), with reporting financial years from 1 July – 30 June.

The period 2005 to 2016 is the R&D Phase. In this Phase, expenses far exceed revenues, and net cash flow from operations is negative as SCENESSE® was developed; clinical studies undertaken and completed; and regulatory approvals sought and obtained. External funding of the business was essential during this period and CLINUVEL achieved this through several self-managed capital raisings totaling A\$94m between 2006 and 2016.

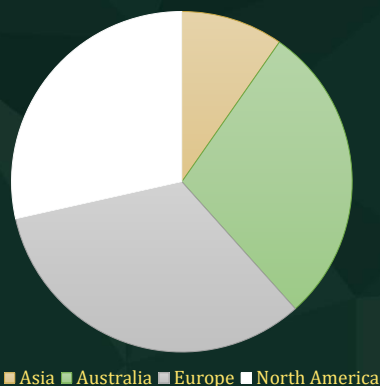
The cost of developing SCENESSE® of A\$154m is the sum of expenses in the 2005-2016 period. This is much lower than the over US\$1bn cost often associated with pharmaceutical drug development. The Company's spending never exceeded A\$16M in any given year of the R&D phase.

The Italian government listed SCENESSE® for reimbursement under a special access scheme in 2010 for EPP – this was our financial proof of principle. In 2012, Swiss insurers agreed to reimburse the cost of treatment of EPP patients under a special access scheme.

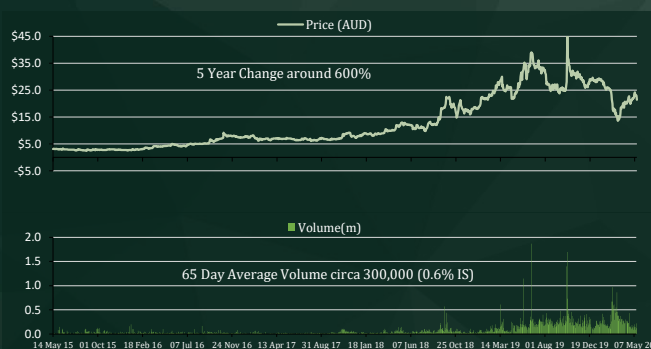
The Commercial Phase formally commenced when CLINUVEL started distribution under the European marketing authorization in June 2016. FY2017 was the first full financial year of commercial operations. You can see the rising trend in revenues relative to expenses and positive net cash from operations in the FY2017-FY2019 period. Our first profit was recorded in FY2017, followed by a higher profit in FY2018 and a rise in FY2019. We also declared a dividend in FY2018 and FY2019. We recorded our eighth consecutive half year profit in the December 2019 period, our cash balance is over A\$60m and we are debt free; arguably, a flawless balance sheet compared to our peers. I will not say more, since our philosophy is not to do the talking, but let our steady progress be discovered.

Shareholder Register and Trading

Geographic Distribution, %



Share Price and Trading Volume (ASX:CUV)



We have many longstanding, supportive shareholders and, in recent years, new shareholders who have joined CUV for the next phase of CLINUVEL's growth.

A snapshot of the geographic distribution of our shareholders shows the largest concentration is in Europe, with similar concentrations in Australia and the United States. The European shareholding reflects our presence on the electronic exchange in Frankfurt, the Xetra-DAX, since 2004 and the investment of many private shareholders through family offices and private banks. In the US, our Level 1 American Depositary Receipt Program which is part of the Nasdaq International Designation has operated since 2004 and this, coupled with rising interest of US institutions, accounts for the strong shareholding here. As a result, our shareholder base is more internationally diverse than many other Australian listed companies.

The share price has progressively increased over time. Over five years there has been a rise of around 600%, with most of this occurring in the last three years. Some of these gains have been impacted by some profit taking following the FDA's October 2019 approval of SCENESSE® for EPP in the USA and into 2020, the general weakness of global share markets due to the impact of the coronavirus pandemic.

Daily trading volume has similarly increased concurrent to our transition to profitable operations and our entry to key Australian Indices, the S&P / ASX 300 in September 2018 and the S&P / ASX 200 in June 2019. The 65-day average volume traded is around 300,000, approximately 0.6% of issued capital.

Strategic Initiatives 2020

SCENESSE® FOR EPP IN APPROVED REGIONS

GROW EUROPE

- Fourth year of commercial operations
- Increase patient treatment access
 - existing and new countries
 - new centers

EXPAND USA

- CEO lead plan & implementation team
- Establish business infrastructure
- Expand US team
- Activate network of Specialty Centers
- Facilitate treatment access with insurers

PROGRESS PIPELINE

- EPP
 - Regulatory approval new regions
 - pediatric formulation
- Vitiligo
 - skin depigmentation disorder with 45 million prevalence
- Topicals
 - for pharmaceutical and OTC use
- Medicinal photoprotection
 - melanocortins in DNA repair

INORGANIC GROWTH

- Active review of value adding opportunities
- Synergistic benefits
- Management to complement CLINUVEL team and culture

There are a range of strategic initiatives to support our future growth and evolution into a diversified and vertically integrated pharmaceutical company providing treatments for multiple patient groups.

We have a grow and expand strategy in the regions for which SCENESSE® is an approved treatment.

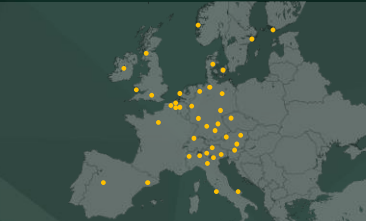
In **Europe** we are working on reimbursement agreements to distribute SCENESSE® for EPP in more European countries; expanding the number of Expert Centers; and increasing patient treatment access.

In the **USA** we have completed the key pre-distribution logistics such as agreement on the pharmacovigilance protocol with the FDA; established our business infrastructure; recruited a local support team; activated a network of Specialty Centers to administer SCENESSE®; and facilitated treatment access with insurers. We commenced first treatment in April 2020, within six months of FDA approval and amidst the global disruption caused by the coronavirus crisis. Further details on our US expansion are provided later in the presentation.

We are also progressing a **Product Development Pipeline** in four key areas: taking SCENESSE® for EPP to new regions and developing a pediatric formulation; developing SCENESSE® as a treatment for vitiligo, a skin depigmentation disorder (discussed later in this presentation); developing topical formulations – both pharmaceutical and over the counter; and progressing medicinal photoprotection through DNA repair of the skin.

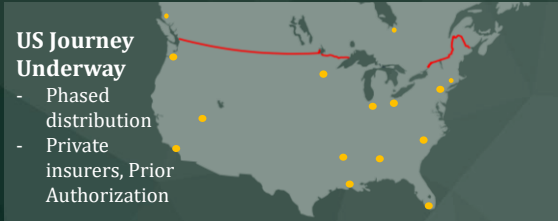
We also monitor and assess **Inorganic Growth Opportunities** as they arise, but this is not a major focus of senior management and the Board. However, for completeness, we are receptive to acquisitions that add value to our business with a management team that must complement the CLINUVEL team and culture.

Grow Europe and Expand USA: SCENESSE® for EPP



European Operations

- Multiple countries
- EPP Expert Centers
- Patients



US Journey Underway

- Phased distribution
- Private insurers, Prior Authorization

CLINUVEL SELF-DISTRIBUTION MODEL

- Long term shareholder return – not diluted by cost of licensing
- Relationship development - direct distribution to hospitals and doctors
- Controlled distribution - preferred by regulator
- Facilitates thorough patient safety profile – via rigorous pharmacovigilance

ECONOMICS and PRACTICALITY

CLINUVEL GLOBAL NET UNIFORM PRICE

- Policy grounded in CLINUVEL's values of transparency, equity and fairness
- Social and political focus on lower drug prices
- Equitable treatment of all payors, hospitals and patients
- US politics “no price rise higher than inflationary rate” [Prescription Drug Pricing Reduction Act, 2019]

LEADING THE WAY

To expand on the growth and expansion of our business in Europe and the USA, it is important to understand our self-distribution model and pricing approach with SCENESSE®.

We have implemented a self-managed controlled distribution model in Europe. This means we supply SCENESSE® direct to Expert Centers, trained and accredited by CLINUVEL in the administration of the product and the pharmacovigilance requirements agreed with the EMA.

The low prevalence of EPP and the finite number of Expert Centers enables us to self-manage distribution in Europe and the USA as well, achieving some key benefits:

- Long-term shareholder return due to a margin that is not diluted by the cost of licensing.
- A direct relationship with hospitals, experts and their teams.
- Satisfies the preference of the regulator.
- Ensures thorough monitoring of patient safety.

Reflecting our corporate values of fairness and equity, CLINUVEL’s price of SCENESSE® is uniform across the countries we supply. We have priced the drug at the lower end of the price spectrum for orphan drugs. The retail price of pharmaceutical drugs has received significant social and political focus, particularly in the USA. CLINUVEL’s approach fits well with clear societal pricing preferences in the USA.

Commercial Distribution: SCENESSE® for EPP in the USA

- Pre-distribution logistics completed within six months of FDA approval
- Over 30 private insurers to reimburse under Prior Authorization, special drug or formulary
- Phased distribution:
 - I: Five Specialty Centers
 - II: Medicare review and decision to reimburse patients
 - III: Thirty Specialty Centers across USA matched to concentrations of EPP patients
- Savings Program
 - Patients apply for assistance through www.scenesse.com
- Pharmacovigilance reporting to FDA for eight years

We are replicating the European distribution model and learnings as much as possible in the USA.

Many of the pre-distribution logistics were completed within six months of FDA approval. This includes the business infrastructure, identification of the correct codes for treatment to ensure smooth operations and reimbursement, initial insurer discussions, and identification of distribution centers.



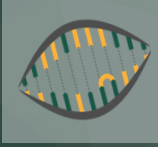
Over 30 private insurers – national and local – have agreed to reimbursement through Prior Authorization, acceptance as special drug or formulary listings. Further discussions are underway.

Distribution is structured across three phases to facilitate patient access.

A Savings Program and dedicated patient and healthcare professional websites have been established to facilitate patient access to treatment.

Pharmacovigilance reporting to the FDA is required over eight years, quarterly in the first three.

Product Development Pipeline

 <ul style="list-style-type: none"> • EPP <ul style="list-style-type: none"> ➢ New regions <ul style="list-style-type: none"> • TGA Australia – decision late 2020 • China – Named Patient Program, Winhealth Pharma collaboration • Others – Japan, Latin America ➢ Pediatric formulation 	<ul style="list-style-type: none"> • Topicals <ul style="list-style-type: none"> ➢ Focus of Singapore subsidiary, VALLAURIX ➢ Pharmaceutical application for vitiligo ➢ Developing OTC products
 <ul style="list-style-type: none"> • Vitiligo <ul style="list-style-type: none"> ➢ Two Phase II studies completed ➢ Type C Guidance meeting with FDA April 2020 ➢ New Phase IIb US study to proceed ➢ View to sNDA 	 <ul style="list-style-type: none"> • Medicinal Photoprotection <ul style="list-style-type: none"> ➢ Assess effectiveness of melanocortins to prevent skin cell mutations ➢ New indication soon

There are four segments to our product development pipeline:

In **EPP**:

- Working on regulatory approvals in new regions:
 - Application to Australian Therapeutic Goods Administration (TGA) lodged and accepted under priority review pathway – decision expected late 2020.
 - China – we commenced a collaboration agreement in April 2020 with a local partner for supply under the Named Patient Program with a view to a new drug application in the future.
 - Other future regions include Japan and Latin America.
- Developing a pediatric formulation of SCENESSE®.

Vitiligo:

- Two Phase II studies completed with promising repigmentation results and safety profile maintained.
- Type C Guidance meeting held 29 April and ongoing discussion with the FDA on final development pathway SCENESSE® for vitiligo, including further clinical evaluation.
- Supplementary New Drug Application (sNDA) submission in future, pending efficacy.

Topicals:

- CLINUVEL's Singapore laboratory continues to progress the development of novel pharmaceutical and over the counter (OTC) products.

Medicinal Photoprotection:

- Early stage evaluation of the effectiveness of melanocortins in DNA repair and the prevention of DNA mutations.
- A new indication in this area is to be announced soon (pending ethics and regulatory approvals).

CLINUVEL's product development pipeline has the potential to enable the Company to assist new patient groups, many with unmet medical needs, and support the long-term sustainability of the business.

SCENESSE® for Vitiligo

Day 0
Baseline

Day 55
After 15 NB-UVB
treatments, 1 implant

Day 111
After 27 NB-UVB
treatments, 3 implants

Day 176
After 40 NB-UVB
treatments, 4 implants

Original Investigation

Afamelanotide and Narrowband UV-B Phototherapy for the Treatment of Vitiligo

A Randomized Multicenter Trial

Henry W. Lim, MD, Pearl E. Grimes, MD, Oma Agbai, MD, Ildefonso Hamzavi, MD, Marsha Henderson, MD, Madeline Haddican, MD, Rita V. Linkner, MD, Mark Lebwohl, MD

VITILIGO JAMA Study

2 Groups:

Light Therapy

Light Therapy and Afamelanotide

KSTP 3 HD

INSIDE YOUR HEALTH

Further comments are made on SCENESSE® for vitiligo as it is one key area of our product development pipeline.

The current standard of care is narrowband ultraviolet B (NB-UVB) phototherapy. The clinical studies we have undertaken to date have compared the results of mono NB-UVB treatment with the combination treatment of SCENESSE® with NB-UVB.

The pictures show the progressive repigmentation of a patient’s legs throughout a Phase II clinical study (CUV102). The patient received treatment with SCENESSE® in combination with NB-UVB phototherapy.

The recent meeting with the FDA is encouraging and we are proceeding with the design of a new study in the USA. We will keep the market informed of our progress.

Future Vision

Evolving into an integrated biopharmaceutical business for sustained long-term growth

- multiple business functions executed in-house
- treatments for multiple patient groups

Foundations

- Strategy for sustainable business success
- Stable, focused management team
- Proven expertise in treatment of genetic disorders

Financial

- Prudent management
- Strong fundamentals
- Self-funding of product development pipeline

EPP

- Grow Europe
- Expand USA
- New jurisdictions
- Develop pediatric formulation

Progressive Pipeline

- Vitiligo
- Topicals
- DNA repair

In summary, CLINUVEL has a rich heritage and a well-defined strategy which underpin our evolution into an integrated biopharmaceutical company for sustained long-term growth. Our business model encompasses ‘in-house’ capabilities and our objective is to provide treatments for multiple patient groups.

THANK YOU

...Questions

Malcolm Bull
Head of Investor Relations
CLINUVEL Group

Level 11, 535 Bourke Street, Melbourne, VIC, 3000

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