SCENESSE®

WORLD'S FIRST SYSTEMIC PHOTOPROTECTIVE

CLINUVEL PHARMACEUTICALS LTD

FROM CONCEPT TO COMMERCIALIZATION

JEFFERIES HEALTHCARE CONFERENCE NEW YORK
6 JUNE 2019

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CEO

ASX: CUV
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Xetra-Dax: UR9

CLINUVEL

SAFE HARBOUR STATEMENT 2019

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, obtain regulatory approvals in major markets and risk to commercialise pharmaceutical products, including our ability to develop, manufacture, market and sell one or more biopharmaceutical products while competition for our products may occur especially SCENESSE® (afamelanotide 16mg); our ability to achieve expected safety and efficacy results through our innovative R&D efforts; the risk of proving effectiveness of the product for 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(s); increased government scrutiny in either Australia, the U.S., Europe 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; and other factors that have been discussed in our 2018 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 and estimates is available on request. Past performance of the company is not an indicator of future performance.

SCENESSE® (afamelanotide 16mg)

- new molecular entity (NME) = synthetic 13 aminoacid peptide (API)
- novel controlled-release subcutaneous injectable implant (polymer)
- dose frequency 60 days
- first-in-class therapy in erythropoietic protoporphyria (EPP)
- world's first systemic photo protective
- ***Alpha-MSH:***

  1. *anti-oxidative*

  2. melanogenic (activates epidermal melanin production)

  3. anti-inflammatory

  4. DNA reparative, photo protective

CLINUVEL – *translational use melanocortins*

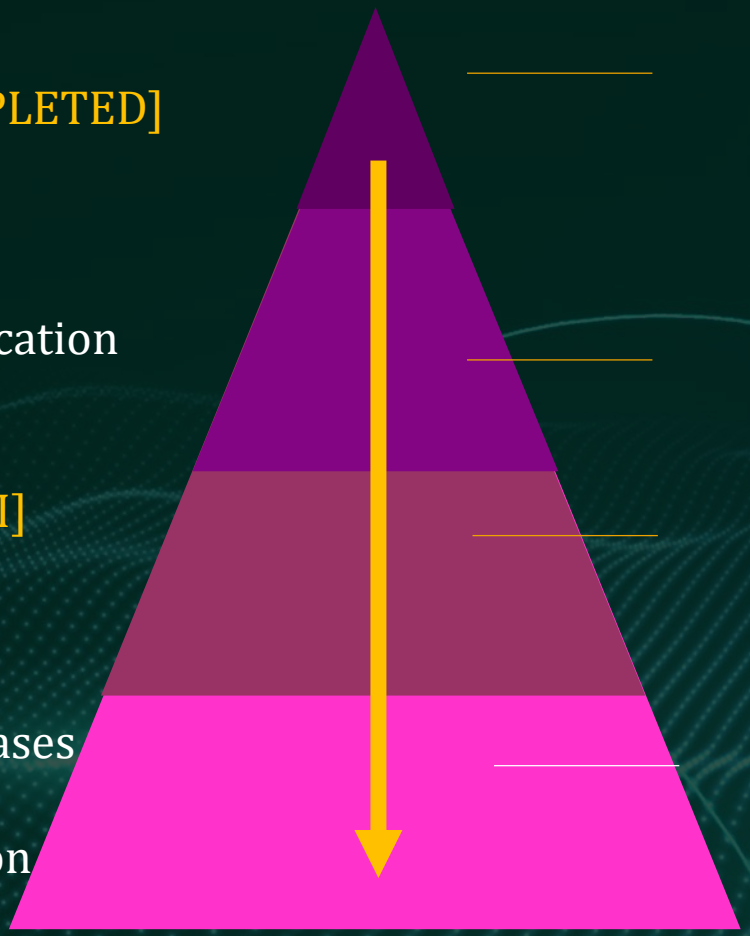
EPP [COMPLETED]

Additional indication

Vitiligo [Ph II]

Metabolic Diseases

Photo protection



Proof of concept - porphyrias (EPP, CEP) 1991- 2019
- pandermal protection, visible light (>408nm)

Photo protection, DNA repair

Systemic repigmentation (total body)
- 1st pharma addressing loss of pigmentation
- positive early safety/efficacy data

Systemic & topical photoprotection
- 2nd generation melanocortins
- additional indications
- complementary product lines – OTC

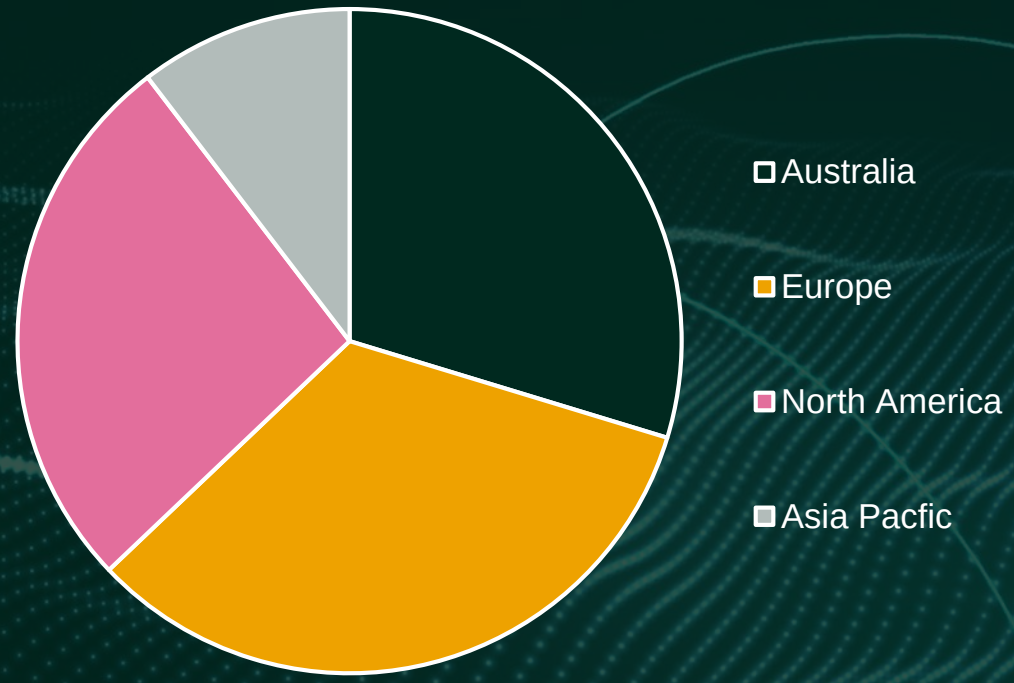
SAFETY

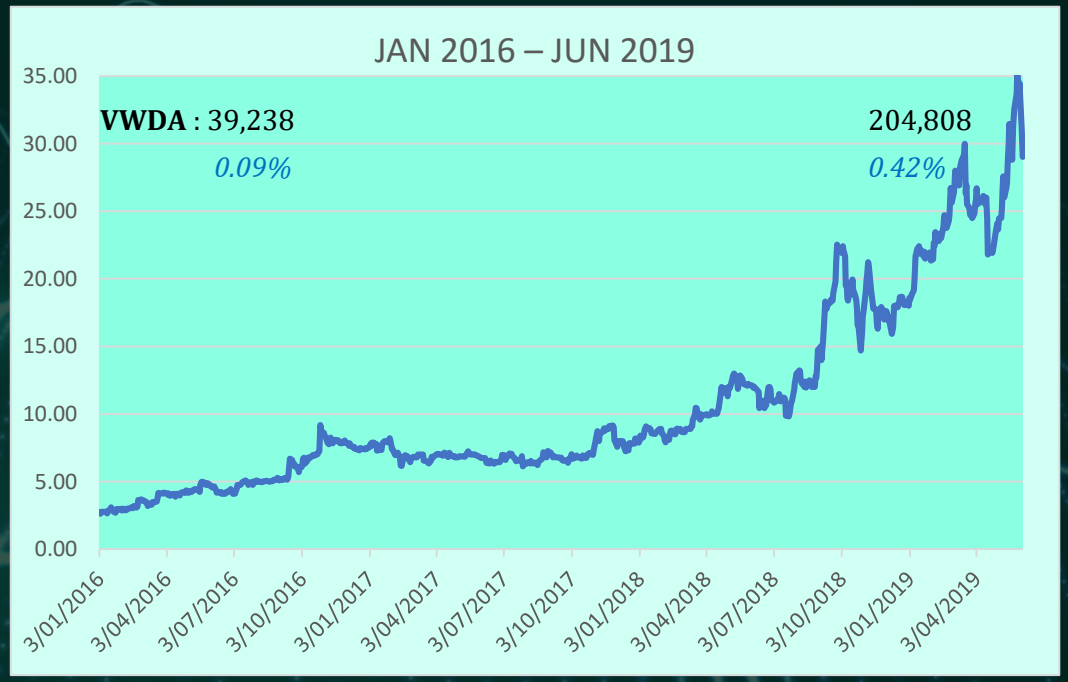
CLINUVEL REGISTER

IPO 2001 Australian Securities Exchange
48,960,633 ordinary shares

ASX-300: CUV [07 SEP 2018]
VWDA 204,808 [0.42% of OSC]

Geographic distribution





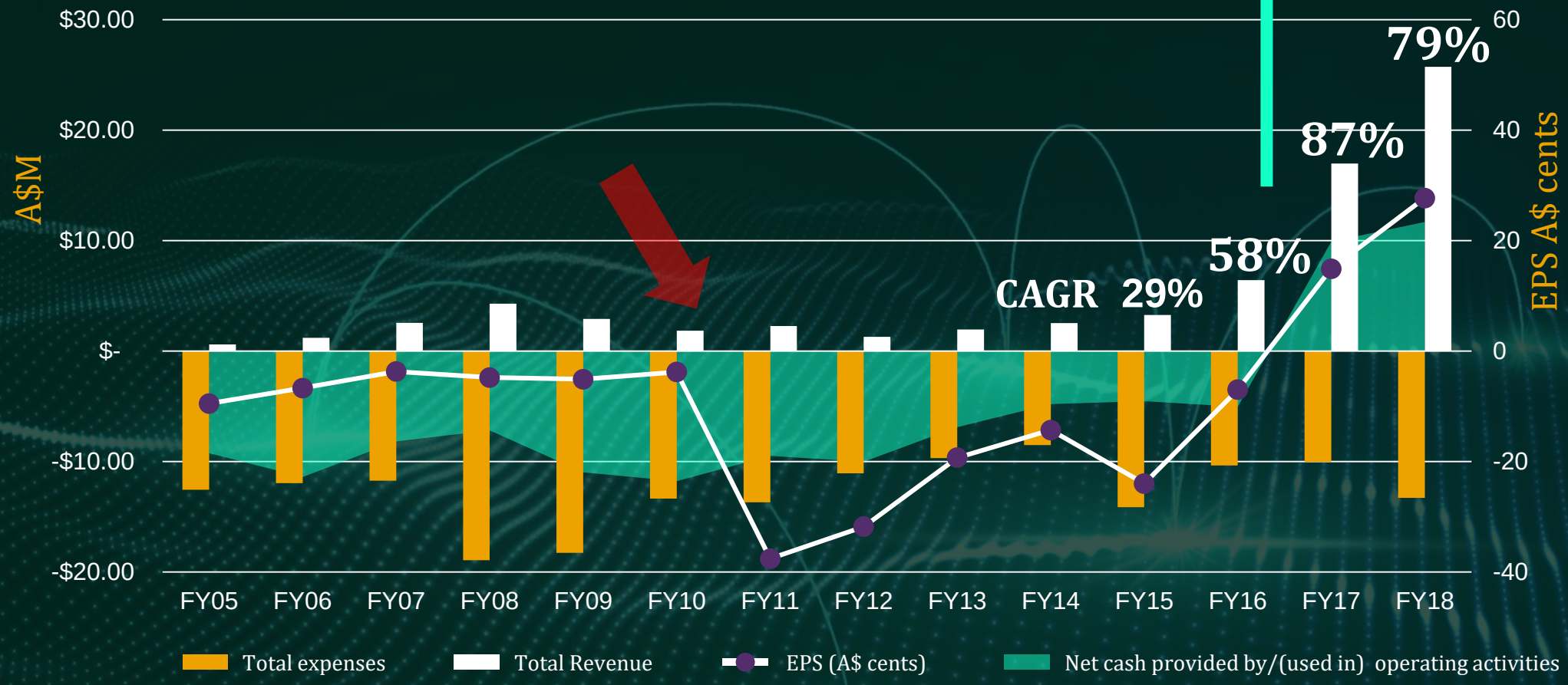
FINANCIALS

R&D 2005-2016

- cost-management
- equity financing
- never below critical cash
- *financial proof of principle 2010*

COMMERCIAL 2016

- *cost-management*
- cash positivity
- profitability
- debt-free
- first dividend FY18

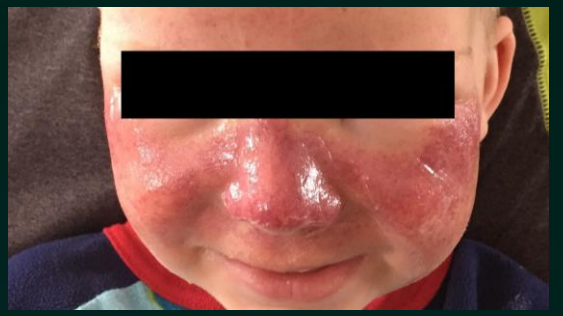


*CUV continues quarterly reporting

**Cash flow statement will reflect seasonal fluctuations due to cyclical treatment period

Product Pipeline

Erythropoietic protoporphyria (EPP)



Phototoxic reaction in an EPP patient.
Image courtesy of the KE family.

- FECH deficiency 18q21, part of the heme metabolic pathway
- Ill-characterized, poorly understood disease
- *Absolute intolerance* to blue/green/UVA/UVB light
  (i) Phototoxicity – incapacitating anaphylactoid reactions, burns
  (ii) High unmet medical need

Isolated patients living reclusive existence

SCENESSE® IN ERYTHROPOIETIC PROTOPORHYRIA (EPP)

- EMA – MA 2014: *standard of care for EPP in European Union, Switzerland*
  - rare genetic metabolic disorder, 1:140,000
  - 17 countries with known EPP patients

- Commercial roll out, focused specialized team
  - disciplines across clinical, regulatory, pharmacovigilance, QA, communications, market access
  - cost effective business model is being replicated in USA

- University medical centers exclusively (*reference centers*)

- Equitable treatment of payors
- Uniform pricing strategy globally
- Health economic impact: US$96,000 per patient [calendar year]

SCENESSE® IN VITILIGO

Clinical Objectives

1. repigmentation face/head/neck
2. follicular response
3. safety profile

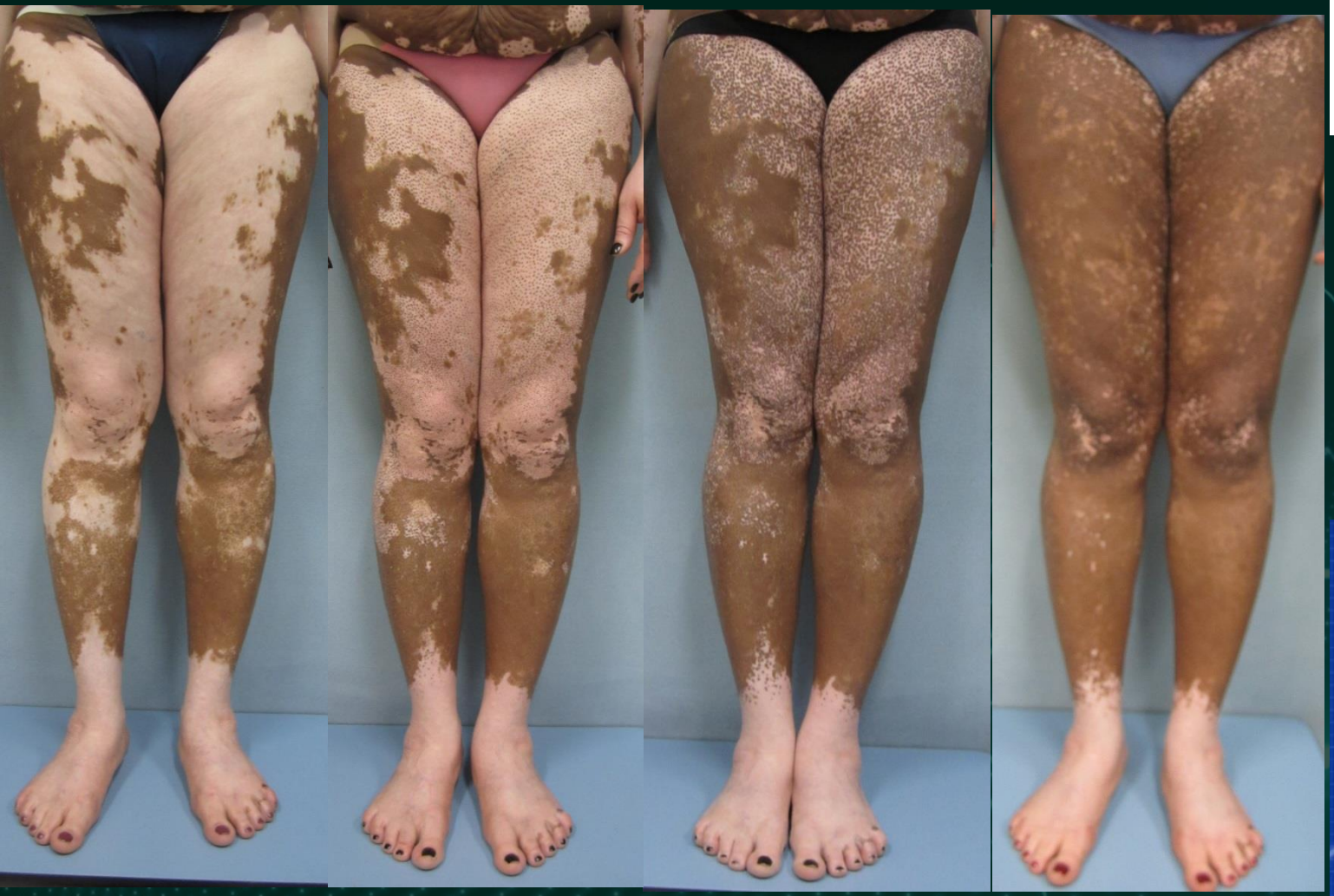
Ph II CUV102 n=54 [2013]

- extent of repigmentation VASI ($p<0.025$)
- time to repigmentation - face ($p=0.01$)
- JAMA Dermatology 2013, 2015
- maintenance of pigmentation at day 336

Ph II CUV103 n=18 [2018]

- repigmentation
  total body, head, neck at day 196 VASI ($p<0.001$)
- maintenance of pigmentation at day 280

SCENESSE® IN VITILIGO



Day 0
Baseline

Day 55
After 15 NB-UVB treatments, 1 implant

Day 111
After 27 NB-UVB treatments, 3 implants

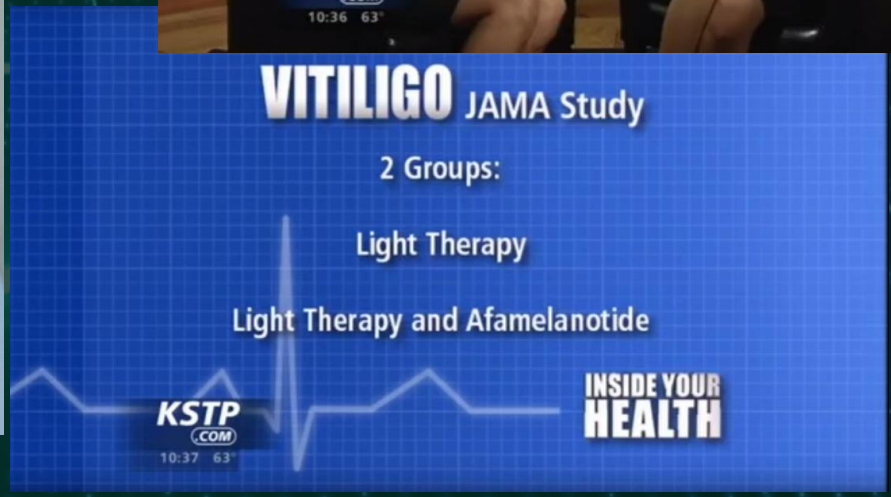
Day 176
After 40 NB-UVB treatments, 4 implants

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; Iltefat Hamzavi, MD; Marsha Henderson, MD; Madelaine Haddican, MD; Rita V. Linkner, MD; Mark Lebwohl, MD



SUMMARY – CLINUVEL PHARMACEUTICALS

- SCENESSE® innovative medical concept – ***world's first systemic photoprotective drug (Rx)***

- Commercialized orphan medicinal product (NME) in Europe
  - Erythropoietic protoporphyria (EPP) – rare genetic metabolic disorder
  - Generating Real World Evidence under "PASS"
  - 94% treatment continuation in EU/CH (as per 1 April 2019)

- SCENESSE® - NDA for prevention EPP — **PDUFA date 6 October 2019**

- Profitability FY2017, FY2018: — **maiden dividend 2018**

- Growth — 1. translational use melanocortins
  2. M&A, in-licensing

"Afamelanotide has radically changed the way I approach my daily life…
This medicine has freed me from the debilitating consequences of EPP
and from fear of suffering them" **Swiss EPP patient**

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GRATITUDE TO CLINUVEL GLOBAL TEAMS FOR 14 YEARS OF TENACITY

CLINUVEL