USA DISTRIBUTION UPDATE SCENESSE®

ORPHAN DRUG – INNOVATION IN PHOTOPROTECTION

MENLO PARK (CA), 23 March 2020

CUV MANAGEMENT
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CLINUVEL

This overview provides an update to financial markets and CLINUVEL's owners **on the distribution plan of SCENESSE® (afamelanotide) in the United States**, following marketing authorization granted by the US Food and Drug Administration (FDA) on 08 October 2019. Comprehensive information is publicly disclosed while various parts of knowhow and expertise are retained for commercial reasons.

The update is provided in lay terms for all stakeholders to learn about SCENESSE® and its use in the United States.
National authorities do not allow content to be made available which can be interpreted as promotion and which would be in breach of relevant legislation, including, but not limited to: The Human Medicines Regulation (2012; UK), the Federal Food, Drug, and Cosmetic Act (1938) and Title 21 of the Code of Federal Regulations Part 202 (USA), the Geneesmiddelenwet (Dutch Medicines Act), and the Arzneimittelgesetz and Heilmittelwerbegesetz (German Drug Law and Act on Advertising in the Field of Health, respectively).

LEGAL NOTICE

This release contains forwards-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, including our ability to develop, manufacture, market, distribute and sell bio/pharmaceutical 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. and/or Europe 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; 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 changes 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 2019 Annual Report. In particular, the systemic effects of COVID-19 and any other pandemic may affect our ability to progress our R&D and commercial efforts to make SCENESSE® available to patients in the European Economic Area, United States or other parts of the world. 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.

As part of **CLINUVEL's Legal Notice**, various risks need to be taken into account when reading through the slide presentation as associated with the Company's business. Risks are highlighted to the audience.

SCENESSE® (afamelanotide)

- Marketing authorization EU [‘14], USA [‘19]
- World’s 1st systemic photoprotective drug
- First Line Therapy in USA and EEA
  - continuation of use >95%[1]
- Provides systemic photoprotection
  - anti-oxidative, vaso-active, anti-phlogistic
- Biodegradable controlled-release implant

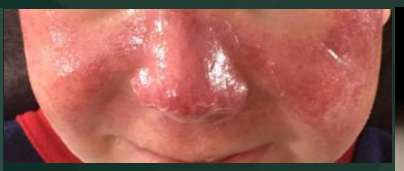
With marketing authorization granted by the leading regulatory authorities the **Food and Drug Administration (FDA) and European Medicines Agency (EMA) in 2019 and 2014** respectively, SCENESSE® became the first pharmaceutical product serving as a systemic photoprotective.
Based on safety observed from two decades of clinical use of SCENESSE® and Real-World-Evidence (RWE) data generated by European and Swiss erythropoietic protoporphyria (EPP) patients, marketing authorization was given for the product in the United States in October 2019.

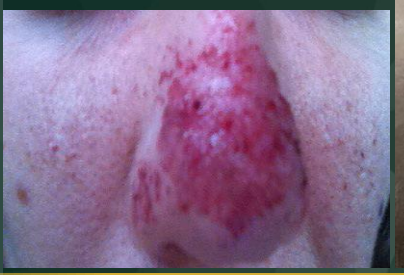
SCENESSE® is accepted as First Line Therapy or (medical necessity) Standard of Care in EPP to prevent phototoxicity (see US Prescribing Information) by providing systemic photoprotection, that is protection against the impact of spectrum of visible and invisible light, thereby protecting the entire body surface.

[1] Rate of continuation year-on-year in Europe for patients enrolled in European EPP Disease Registry.

INDICATION: ERYTHROPOIETIC PROTOPORPHYRIA (EPP)

- Intolerance to light sources
  - ambient, incandescent, outdoors
  - blue/green/UV, peaking at 408nm
- Phototoxicity – 2nd degree burns debilitating anaphylactoid reactions
- Generalized edema, malaise, anxiety
- Conditioned behaviour, social isolation
- Rare disorder, not characterized
  - prevalence 10,000 worldwide





EPP patients suffer from absolute intolerance to light sources and ultraviolet (visible and invisible spectrum of light) from birth.
Patients are lifelong at risk for phototoxic reactions (also called **phototoxicity**), causing 2nd degree burns on exposed areas of the skin.
Patients suffer from generalized edema and malaise, and eventually see scarring after the scalded areas of the skin have healed.
The strong memory of phototoxic episodes leaves patients no choice than to avoid light sources and become **socially isolated**: this results in lifelong conditioned behaviour.
Due to the lack of any effective therapy or prescriptive drug prior to the marketing authorization of SCENESSE®, the disease had been poorly characterized as patients obtained very little clinical attention.

1 Phototoxic reactions, images are courtesy of the KE family (top) and patient NT (bottom).

CHARACTERIZATION OF ERYTHROPOIETIC PROTOPORPHYRIA (EPP)

I. Haematology - genetic metabolic
   - *FECH deficiency18q21 in heme biosynthesis pathway*
   - *IVS3-48C allele trans to the mutation*

II. Accumulation of protoporphyrin IX in tissues (dermis, hepatic tract)

III. Chronic affliction, diagnosed at age 9 (ave.)
   - *unknown pathology causes impairment to infant and family*

IV. Patients receive medical consultation from nine [different] medical specialties

V. Americans with Disabilities Act 2008 – s 503: physical, mental impairment
   - *21 CFR 340.80, 310.305*

EPP is a poorly characterized disease, which has attracted very little clinical research. The genetic deficiency is well known with ferrochelatase gene mutated in the IVS3-48 C. The defect in the heme biosynthesis pathway leads to the accumulation of the metabolic product **protoporphyrin IX [PPIX]**, predominantly in the skin and liver.

The disorder is chronic in nature and no cure is available at present. Patients are typically diagnosed after nine years of delay, whereby the disease poses a significant burden on the juvenile patients and families. Children are unable to express the internal ordeal and do not understand the extent of “pain” suffered upon the omnipresent light sources.

Due to the lack of previous treatment options, nine different medical specialties have consulted the EPP patients without having a therapy to offer. EPP is regarded as a handicap, disability in the context of rare invisible disorder. In the United States, the Federal government defines "disability" according to the nondiscrimination laws. The Americans with Disabilities Amendments Act (ADAAA) Americans with Disabilities Act, Section 503 of the Rehabilitation Act of 2008 provides the definition as a person with a disability, who

(1) has a physical or mental impairment that substantially limits one or more "major life activities“,
(2) has a record of such an impairment, or
(3) is regarded as having such an impairment.

The FDA 21 CFR defines impairment along the same lines as the ADAAA.
More than 35 million Americans experience activity limitations owing to chronic health problems or impairments, and many of them are deprived economically and socially due these limitations.

EPP is acknowledged as a disease posing a lifelong disability.

SCENESSE® ORPHAN DRUG

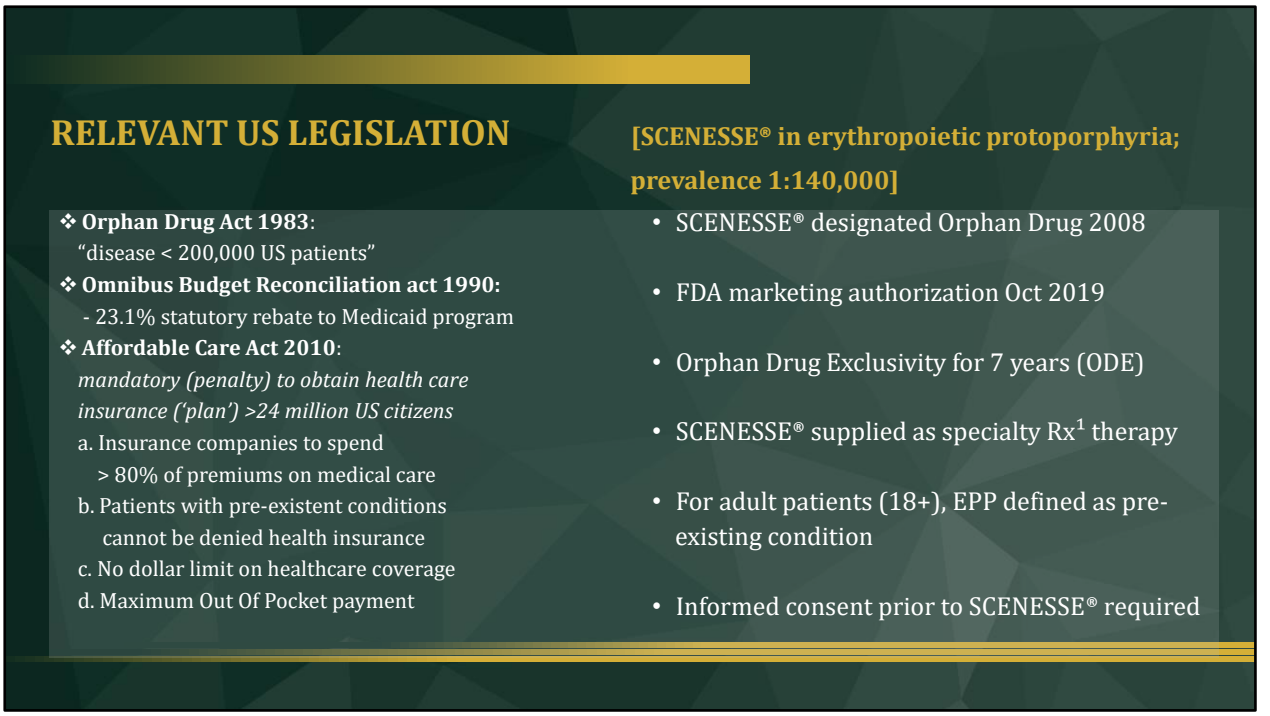
Context and relevant facts

- Estimated 6,000 orphan diseases in the USA
- 539 US FDA approved orphan drugs [ODs][1]
- 30 million US citizens suffer from an orphan disease[2]
- 25% of orphan drugs treat < 5,000 patients[3]
- 1: 140,000 are affected by EPP [4]

Global hotspots of reported EPP prevalence[5]

A context is provided to SCENESSE® as the **first systemic photoprotective drug** among other orphan drugs in the United States.
Approximately 9% of all orphan diseases have now found a preventative or curative therapy, whereby of therapies are still in development for 20% of ODs.
The legislative changes have had some effect to incentivize pharmaceutical manufacturers to enter smaller markets, however there is much ground to be covered yet by the pharmaceutical sector.
In the United States, generally speaking approximately 25% of orphan drugs treat less than 5,000 patients per disease entity.

[1] Since enactment of Orphan Drug Act in 1983.
[2] Source Evaluate Pharma 2019, IQVIA Annual Report 2019
[3] Ollendorf, Chapman & Pearson (2018). Evaluating and Valuing Drugs for Rare Conditions: No Easy Answers. *Value Health*. 21(5):547-552; IQVIA National Sales Perspectives 2019.
[4] The prevalence of EPP in the United States is based on information shared by the US FDA in 2016: [fda.gov/EPPworkshop]
[5] Balwani et al (2019). Erythropoietic Protoporphyria and X-Linked Protoporphyria: pathophysiology, genetics, clinical manifestations, and management. *Mol Gen Met.* 128(3): 298-303. Edel et al (2019). Epidemiology of Cutaneous Porphyria in Israel: A Nationwide Cohort Study. *JEADV*. 34(1):184-187; Elder et al (2013). The incidence of inherited porphyrias in Europe. *JIMD*. 36(5):849-857; Marko et al (2007). Erythropoietic protoporphyria patients in Slovenia. Acta Dermatovenerologica Alpina, Pannonica, Et Adriatica. 16(3):99-102; Mykeltun et al (2014). Porphyrias in Norway. *Tidsskrift for Den Norske Laegeforening*. 134(8):831-836. CLINUVEL in-house data.



The Orphan Drug Act enacted in 1983 provided Congress the power to launch a program incentivizing companies to develop pharmaceutical products intended for the treatment, prevention or diagnosis of a rare disease or condition, which is one that affects less than 200,000 people in the United States.

The Omnibus Budget reconciliation Act of 1990 introduced a subsection providing for the Medicare and Medicaid Budget Reconciliation Act to be put in place in 1993. Relevant to the SCENESSE® treatment is the provision for Outpatient Hospital Services (Subchapter B), the Part B Premium (Subchapter D) and Part II Outpatient Prescription Drugs (section 5106).
Additionally, the Act (Sec. 5107) repeals the prohibition on the imposition of Prior Authorization controls on new drugs for the first six months after FDA approval.
In 2020, the statutory rebate is 23.1% of the Average Manufacture Price (AMP) for Medicaid patients, to be paid by pharmaceutical manufacturers to Medicaid.

The Affordable Care Act lays down the mandatory requirement for healthcare insurance for US citizens and residents.
Relevant to SCENESSE® is the individual insurance plan taken out by patient (employee) and employer determining the:
(i) Deductibles;
(ii) Maximum out of Pocket Expenses (annual); and
(iii) Premium.

US citizens and residents are obliged to have qualifying healthcare coverage, unless they fall under exemption criteria. For the months of the year the citizens are not insured, a penalty applies unless the exemption applies.

[1]Rx prefix requires practitioner's supervision owing to a drug's toxicity or potentiality for harmful effect, or method of use. The labeling indicates that it is by prescription-only.

UNITED STATES PHARMACOVIGILANCE SCENESSE® I

US PRESCRIBING INFORMATION:

Indication: *"to increase pain-free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria"*

i. Defined **Adverse Events** of interest

ii. Dosage, Administration: one implant every 2 months by a healthcare professional trained by CLINUVEL

iii. Warnings: full body skin examination (twice yearly) to monitor pre-existing and new skin pigmentary lesions

iv. Patient Counseling: maintain sun and light protection measures during treatment with SCENESSE® to prevent phototoxic reactions related to EPP

The US PRESCRIBING INFORMATION reads:
SCENESSE® should be administered by a healthcare professional, all healthcare professionals should be proficient in the subcutaneous administration procedure and have completed the training program provided by CLINUVEL prior to administration of the SCENESSE® implant [see Dosage and Administration (2.2)]. Additional information, including a demonstration video will be available on www.scenesse.com as of 15 April 2020; the additional information has not been evaluated or approved by the FDA.

UNITED STATES PHARMACOVIGILANCE SCENESSE® II

Post-marketing commitments to FDA stipulate:

- FDCA 505(o)(3)[1]
  - (i) **Follow up of patients for a minimum of 8 years [Oct 2027]**
    - continuous, systemic longitudinal observation
  - (ii) **Global EPP Disease Registry**
    - Prospective, longitudinal, registry based observational study (long-term safety)
    - Post-marketing reporting (PMR) of adverse drug experiences (21 CFR 314.80 and 314.81)
    - Annual report on PMR status to FDA (FDCA Sec 506B and 21 CFR 314.81(b)(2)(vii)
    - Interim Reports to the FDA every 2 years to 2028
    - Quarterly PADERs[2] to FDA or harmonized PBRER[3] safety reports to FDA/EMA
  - (iii) **Data Safety Monitoring Board**
  - (iv) **Controlled distribution to trained & accredited US centers**
    - Multidisciplinary care
    - Dermatology examinations annually [2], liver function [1]

[1] Federal Food, Drug and Cosmetic Act (FDCA) describes the post-marketing commitments as the Sponsor's obligation to provide more safety data during a defined period of time following marketing authorization in order to ensure maximum surveillance of patients.

The Global EPP Disease Registry (GEDR) will assist in collecting not only US data but data worldwide under conditions of use (of the drug) in EPP; it is seen as a regulatory breakthrough in that the FDA had accepted the Sponsor's rationale in harmonizing the data and long-term follow-up.
SCENESSE® will be distributed in a controlled manner, as per CLINUVEL's commitments to the European Medicines Agency (EMA) and FDA. Safety is the best guarantee for long-term value for patients, healthcare providers and shareholders. Part of the pharmacovigilance is the conduct of a dermatology examination twice per annum and a liver function evaluation once per calendar year.
Both Periodic Adverse Drug Experience Report[2] and Periodic Benefit Risk Evaluation Report[3] are required.

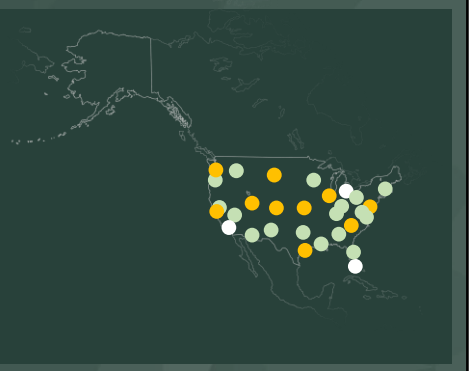
PHASED USA - DISTRIBUTION PLAN SCENESSE® I

Distribution of SCENESSE® in three phases:

Phase I – 2020: First selected centers provide drug access
[white]

Phase II- 2021: Expansion of trained & accredited centers
[yellow]

Phase III – 2022: Maximum of 30 treatment centers
[green]



In a model whereby CLINUVEL takes the treatment to the EPP patients, decentralization is the aim. CLINUVEL's intention is for patients to gain access to treatment *within 5 hours* of their homes; the phased distribution plan aims to arrive at this at the end of the phased program.
Central to CLINUVEL's plans is to minimize the travel imposed and time to be taken off work by EPP patients. Medical centres of expertise have been selected and will undergo training, accreditation and will require sufficient staff to provide ongoing care for the EPP patients. Most expert centers are not familiar with, or used to, long-term follow up of their patients and this requires professional attention from the CLINUVEL staff. CLINUVEL is ultimately responsible for the pharmaceutical product.

In many instances, EPP patients will need to travel after hours to avoid conditions of risk of phototoxicity: from European observations and US clinical trials it was seen that patients seeking treatment will avoid light sources, sun and daily exposure.
Minimizing travel distances to treatment centers, is intended to facilitate access and avoid patients losing a day of employment or study. At a dose interval of one SCENESSE® injection per two months, the burden on patients seeking treatment multiple times per calendar year can be substantial.
In a second phase, as of 2021 further centers will be added, providing access to the northern, southern and central region.
In the third phase, all of the maximum 30 selected US EPP centers will be able to provide treatment and upload the clinical data in the GEDR for regulatory analyses.

PHASED USA - DISTRIBUTION PLAN SCENESSE® II

Distribution of SCENESSE® in three phases:

Phase I:	**Prior Authorization [PA] for insured patients** - patients to seek direct contact with individual insurances for treatment under the Plan - prescribing physician required to agree treatment of patients for 1 year under PA
Phase II:	**Medicare to complete review of SCENESSE®:** - Local Coverage Determination - National Coverage Determination
Phase III:	**All USA centers involved (approx. 30 trained & accredited)**

The distribution of SCENESSE® will take place in three phases.
In phase I, EPP patients will seek verification from their insurance providers to be eligible to receive SCENESSE® treatment under the insurance plan (the Plan). Under their current insurance plan, the terms & conditions of treatment will be reviewed by patients and insurance provider.
As part of the treatment to be administered, the prescribing physician is required to obtain Prior Authorization [PA] from the relevant insurance company of the individual patient.
For Phase II, Medicare will need to complete its review of the SCENESSE® dossier and opine on National and Local Coverage for the treatment, as to be confirmed by the Centers for Medicare & Medicaid Services (CMS).
Phase III will include all selected US EPP centers providing treatment and uploading pseudonymized data in the Global EPP Disease Registry.

PHASED USA - DISTRIBUTION PLAN SCENESSE® III

Distribution of SCENESSE® in three phases:

I. US Distribution Center responsible for
- direct transport under cold storage (2-8^{0}C) to pharmacy of hospital/medical center

II. Trained & accredited treatment centers in
(i) Detroit, MI
(ii) Los Angeles, CA
(iii) Aventura, FL

III. EPP patients make direct contact with prescribing physician (trained/accredited)

IV. Call Center toll-free 24/7 for patient queries, spontaneous safety reporting

The launch of SCENESSE® in the United States is divided in three phases.

During Phase I, an US distribution center will be responsible for direct transport to hospitals and medical centers trained & accredited by CLINUVEL.
Three centers are selected for distribution during Phase I.
Patients will need to make direct contact with the prescribing physician.
A Tollfree number has been established for patients to ask relevant treatment-related questions, and a portal to reports Adverse Drug Reactions following the administration the drug product. The first US patients receiving treatment will provide feedback for the Call Centre to improve, optimize and add to the information provided (150 days).
The Call Center will assist patients to seek information and report adverse drug related events (side effects).
As of April a 24/7 Call Center toll-free number will be made public .

During Phase I, in the first instance three treatment centres will administer SCENESSE®:
(i) Detroit, Michigan
(ii) Los Angeles, California
(iii) Aventura, Florida

EPP patients will find the relevant information on www.scenesse.com **as of 15 April.**

PHASED US DISTRIBUTION PLAN SCENESSE® IV

Phase I

Status: 29 Healthcare Insurances agreed to Prior Authorization[1] [PA] of SCENESSE®.

I. US Healthcare Insurers[2], examples:

Blue Cross Blue Shield	Network Health
Florida Blue	1199SEIU Benefit & Pension Funds
Independence Blue Cross	UAH Health Insurance
AmeriHealth	Health Well Foundation
Medical Mutual	NH Healthy Families

II. Prescribing physician to apply for PA on behalf of EPP patient to insurance provider

III. Insured patients will obtain treatment under PA in the selected centres, pending
- proof of diagnosis
- written proof of insurance cover

[1]During Phase I of the US distribution, treatment will be provided under **Prior Authorization**. Prior Authorization for SCENESSE® is a decision by a payor that a healthcare service, treatment plan, prescription drug, or durable medical equipment is medically necessary and is included in a member's (patient's) coverage

In total 29 insurance companies across 16 states have so far agreed to SCENESSE® therapy under PA while further investigation is being performed to assess the value of the treatment offered, as well as an inventory of eligible EPP per insurance provider.

Since no insurance company has provided care of EPP patients, the therapy is being reviewed by Drug Utilization Boards and Pharmacy and Therapeutics Committees to reach formulary decisions to be expected later in the year.

Under PA, each insurance company takes a decision on reimbursement on a case by case basis concerning complex treatments ('utilization process management'). For a treatment decision to be deemed positive, the prescribing physician has to lodge a written request to the insurance, whereby average replies occur between 3 and 5 working days (reference: Blue Cross Blue Shield, Aetna, Cigna).

[2] The list of insurances published is not exhaustive and subject to changes as more insurances are reviewing the prescription of SCENESSE® within hospital setting and more are expected to grant treatment under PA.

CODING OF SCENESSE® - R_X SPECIALTY TREATMENT

I.	**ICD-10-CM**	
	E80.0	Hereditary erythropoietic porphyria
II.	**CPT Code**	
	17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
III.	**J-Code**	
	J3490	Drugs unclassified injection
IV.	**NDC**	
	73372-0116-1	16 mg of afamelanotide, bioresorbable implant.

The ICD-10-CM E80.0 (International Classification of Diseases, 10th Revision, Clinical Modification) is provided by the Centers for Medicare and Medicaid Services (CMS) and the National Center for Health Statistics (NCHS), for medical coding and reporting in the United States. The ICD-10-CM is based on the ICD-10, the Statistical Classification of Disease published by the World Health Organization (WHO). It contains codes for diseases, signs and symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or diseases.

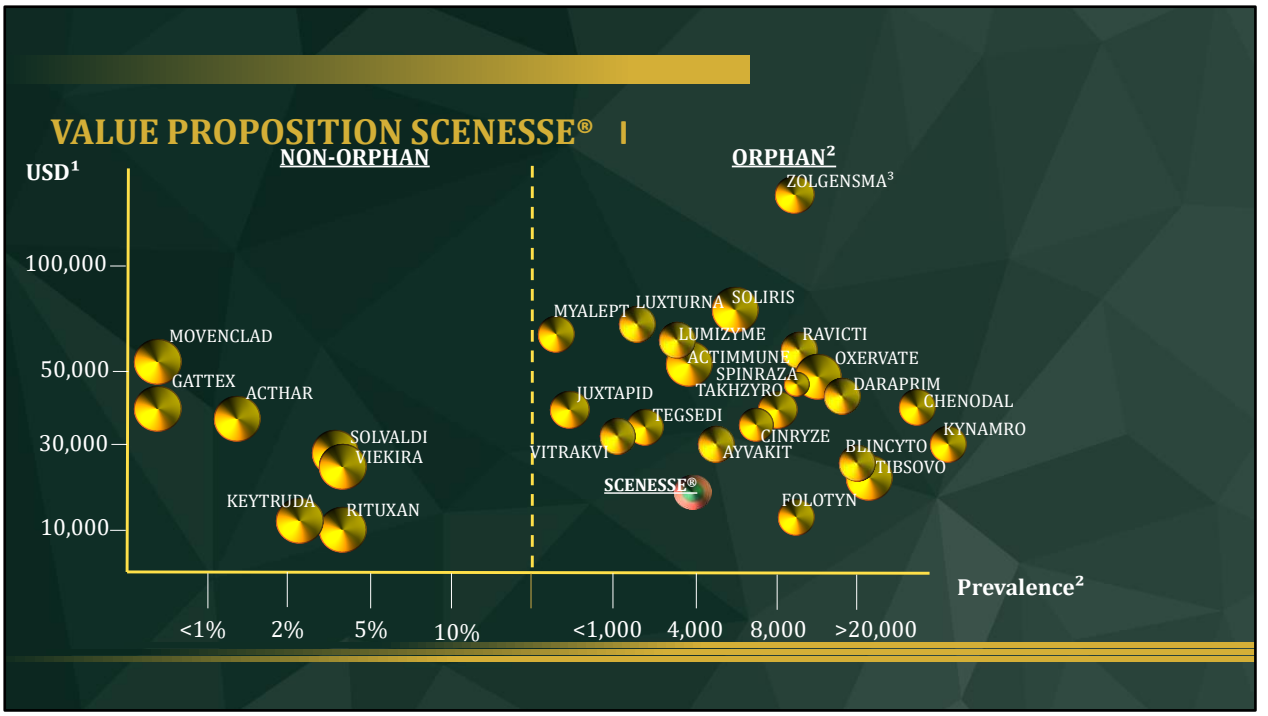
The E80.0 code belongs to the Metabolic Disorders category. This code is applicable to erythropoietic protoporphyria and congenital erythropoietic porphyria.

The Healthcare Common Procedure Coding System (HCPCS) is a standardized code system for medical providers to submit healthcare claims to Medicare and other health insurances in a consistent and orderly manner. HCPCS comprises two medical code sets, HCPCS Level I and HCPCS Level II.

HCPCS Level I consists of the Current Procedural Terminology (CPT) code set. It is used to report procedures and services to federal and private payers for reimbursement of rendered healthcare. CPT is updated annually by the American Medical Association (AMA).

HCPCS Level II is the national procedure code set for healthcare professionals when filing health plan claims for medications, etc. Under the HCPS Level II code is a subset called the J-codes, used to identify injectable drugs. These codes are assigned by the Centers for Medicare & Medicaid Services (CMS). J-codes typically includes drugs that cannot self-administered, are reasonable and necessary for the treatment of the injury or illness and considered effective by the FDA.

NDC stands for National Drug Code. It is a unique 10-digit or 11-digit, 3-segment numeric identifier assigned to each medication listed under Section 510 of the US Federal Food, Drug and Cosmetic Act. The first segment is the labeler code assigned by the Food and Drug Administration (FDA) upon submission of a Labeler Code Request. The second segment, the product code, identifies a specific strength, dosage form, and formulation for a particular entity. The third segment, the package code, identifies package forms and sizes.



A comprehensive **overview of 28 drug prices in the United States** is given reflected as *cost per dose per month* as of June 2019 [valid to March 2020]. [a] These 28 were selected from recent industry press and reports from financial services as drugs commanding the highest price per month of treatment in 2019 and 2020.

The value proposition for SCENESSE® in the United States is put in context of non-orphan (>200,000 patients) and orphan therapies (<200,000 patients). Although SCENESSE® is not listed among high drug prices in the United States, the analyses are providing US insurers and Centers for Medicare & Medicaid services a first view on the drug's positioning.

In distinguishing two groups, in absolute terms the highest cost per treatment is found in the orphan drug group with ZOLGENSMA from Novartis and MOVENCLAD by EMD Serono in the non-orphan group. In relative terms, the highest number of patients worldwide are found in the non-orphan group with drugs like KEYTRUDA (lung, head-neck cancer and melanoma) and RITUXAN (rheumatoid arthritis and Non-Hodgkin Lymphoma).

Among orphan drugs, SCENESSE® is positioned as the second lowest cost per treatment per month, with a prevalence of disease (EPP) in the United States of 2,335 based on a US population of 327 million and a prevalence of 1:140,000 [fda.gov/EPPworkshop]. The lowest priced drug in the orphan group is Folotyn® for the treatment of peripheral T-Cell lymphoma with approximately 2,180 patients in the US.

[a] FiercePharma, Global Pharmaceuticals Report E&Y 2019, E&Y Newsroom, Goldman Sachs Annual Overview Lifesciences 2019, MTS overview for the Year 2019

[1] Cost per month for each pharmaceutical treatment course in the United States in 2020 as listed under Medi-Span Rx.

[2] Sources: www.cdc.gov, Evaluate Pharma 2019, Tufts Center for the Study of Drug Development, GoodRx.com, drugs.com, AHIP.

[3] ZOLGENSMA is priced at US$177,083 per month or US$35,416 if an agreement is reached with the insurer for a treatment of 5 years, regarded as the most expensive drug available in the USA.

VALUE PROPOSITION SCENESSE® II

- SCENESSE® amidst 28 selected drugs in USA
- Insurers bill SCENESSE® under "medical benefit"
- SCENESSE ® listed under PA as a preventative therapy
- Start distribution SCENESSE® to US EPP patients planned after 15 April 2020.
  Pending COVID-19

Monthly Cost 29 DRUGS[1]	
>$150,000	1
$100,00 - $150,000	0
$ 50,000 -$100,000	7
$ 40,000 -$ 50,000	7
$ 30,000 -$ 40,000	6
$ 20,000 -$ 30,000	3
$ 10,000 -$ 20,000	4
TOTAL	28

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The highest cost drug is ZOLGENSMA®.
Between $50,000 and $100,000 there are 7 drugs (Soliris®, Myalept®, Ravicti®, Movenclad®, Actimmune®, Lumizyme®, Luxturna®)
In the brackets between $40,000 to $50,000 per month per treatment course, 7 drugs are listed (Oxervate®, Takhzyro®, Daraprim®, Juxtapid®, Cinryze®, Chenodal®, Gattex®).
Between $30,000 and $40,000 per month there are 6 drugs (HP Acthar®, Tegsedi®, Vitrakvia®, Ayvakit®, Kynamro®, Spinraza®).
In the bracket of $20,000 and $30,000 per month there are 3 drugs (Solvaldi®, Viekira®, Tibsovo®).
In the bracket between $10,000 and $20,000 there are 4 drugs (Keytruda®, Rituxan®, Fotolyn®, Blincyto®).
The SCENESSE® treatment in EPP is put in context of 28 orphan and non-orphan drugs as reflected in a monthly cost per treatment.

In summarizing the status of SCENESSE®, the first EPP patients may obtain SCENESSE® after 15 April 2020, conditional to written confirmation by the insurance providers and PENDING THE EFFECTS OF THE COVID-19 PANDEMIC on the hospitals' ability to provide adequate clinical care.

CLINUVEL CO-PAYMENT SAVINGS PROGRAM

TO US CITIZENS-RESIDENTS

April 15th, 2020: website www.scenesse.com:

I CLINUVEL provides a co-payment savings program

II Insured patients eligible

III Terms & conditions, eligibility criteria to be revealed

IV **Individual application to be made to CLINUVEL after April 15th, 2020**

On 8 October 2019, CLINUVEL informed all stakeholders that it would be able to distribute SCENESSE® to US patients by the end of 2020. The CLINUVEL team is pleased to share today that **after 15 April**, patients will be able to start the progress to apply for CLINUVEL's CO-PAYMENT SAVINGS PROGRAM.

Individual applications will need to be made, whereby terms & conditions will apply to each patient on a case by case basis.
EPP patients with *commercial or private health insurance* may be eligible, depending on the terms of each insurance policy.

CLINUVEL aims to assist all EPP patients to gain access to treatment, but cannot guarantee that all US citizens and residents will be able to receive treatment. CLINUVEL will work with all EPP patients to find reasonable solutions within the confounds of US legislation.

Thank you for your attention, we appreciate the many requests CLINUVEL has received from US patients, and we wish you strength in these difficult times.

The CLINUVEL team sincerely hopes that EPP patients will be able to receive SCENESSE® from April and that the COVID-19 is not affecting patients or their families or the ability to obtain systemic photoprotective treatment, enabling the affected patients to lead a normal life.