Presentation to international porphyria patient group

Melbourne, Australia and Leatherhead, UK, February 8, 2016

Clinuvel Pharmaceuticals Ltd (**ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY**) presented to an international porphyria patient meeting, held in Rotterdam, the Netherlands, on February 6, 2016. The presentation and speaking notes are appended to this announcement.

- End -

About Clinuvel Pharmaceuticals Limited
Clinuvel Pharmaceuticals Ltd (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) is a global biopharmaceutical company focused on developing drugs for the treatment of a range of severe disorders. With its unique expertise in understanding the interaction of light and human skin, the company has identified patient populations with a clinical need for photoprotection and for repigmentation. The worldwide prevalence of these patient groups range from 5,000 to 45 million. Clinuvel's lead compound, SCENESSE® (afamelanotide 16mg), was approved by the European Commission in 2014 for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP). Headquartered in Melbourne, Australia, Clinuvel has operations in Europe, Switzerland, the US and Singapore.
For more information go to http://www.clinuvel.com.
SCENESSE® is a registered trademark of Clinuvel Pharmaceuticals Ltd.

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Forward-Looking Statements
This release to the Australian Securities Exchange and to press may contain forward-looking statements, including statements regarding future results, performance or achievements. These statements involve known and unknown risks, uncertainties and other factors which may cause Clinuvel's actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Some of the factors that could affect the forward-looking statements contained herein include: that the FDA may require additional studies beyond the studies planned for product candidates or may not provide regulatory clearances, including for SCENESSE®; that the FDA may not provide regulatory approval for any use of SCENESSE® or that the approval may be limited; that Clinuvel may never file an NDA for SCENESSE® regulatory approval in the US; that the Company may not be able to access adequate capital to advance its vitiligo programs; that the Company may not be able to retain its current pharmaceutical and biotechnology key personnel and knowhow for further development of its product candidates or may not reach favourable agreements with potential pricing and reimbursement agencies in Europe and the US.

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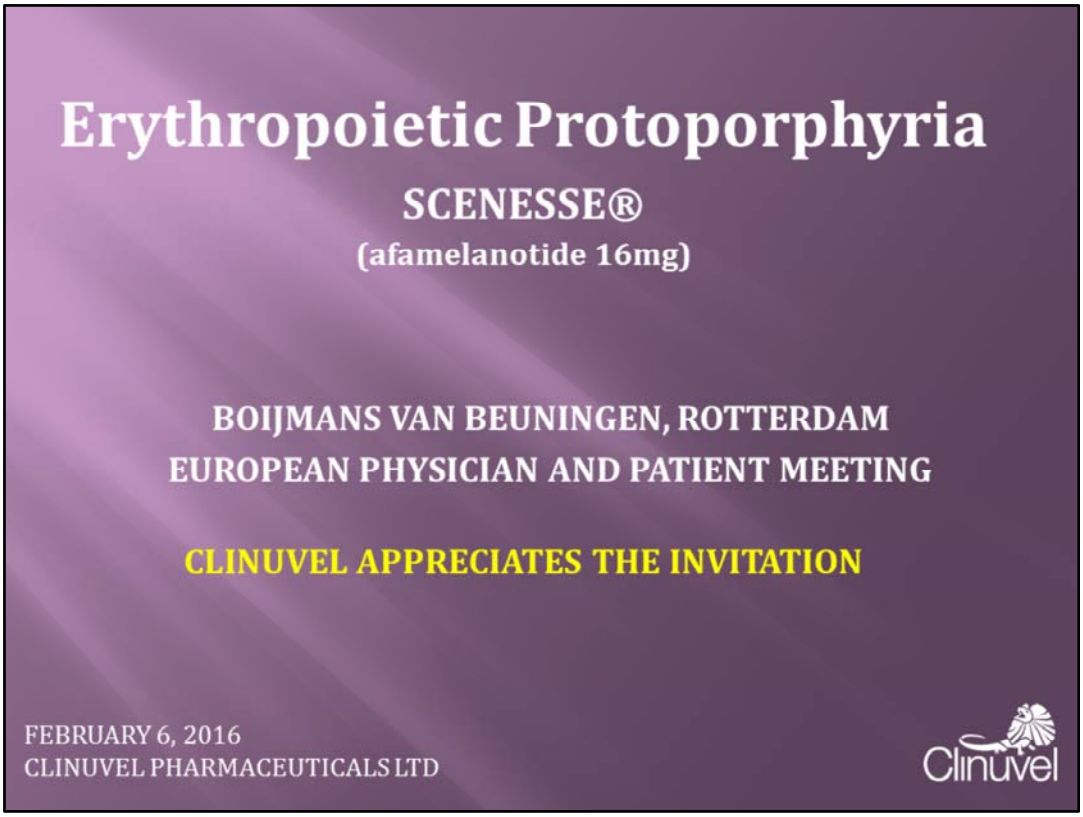
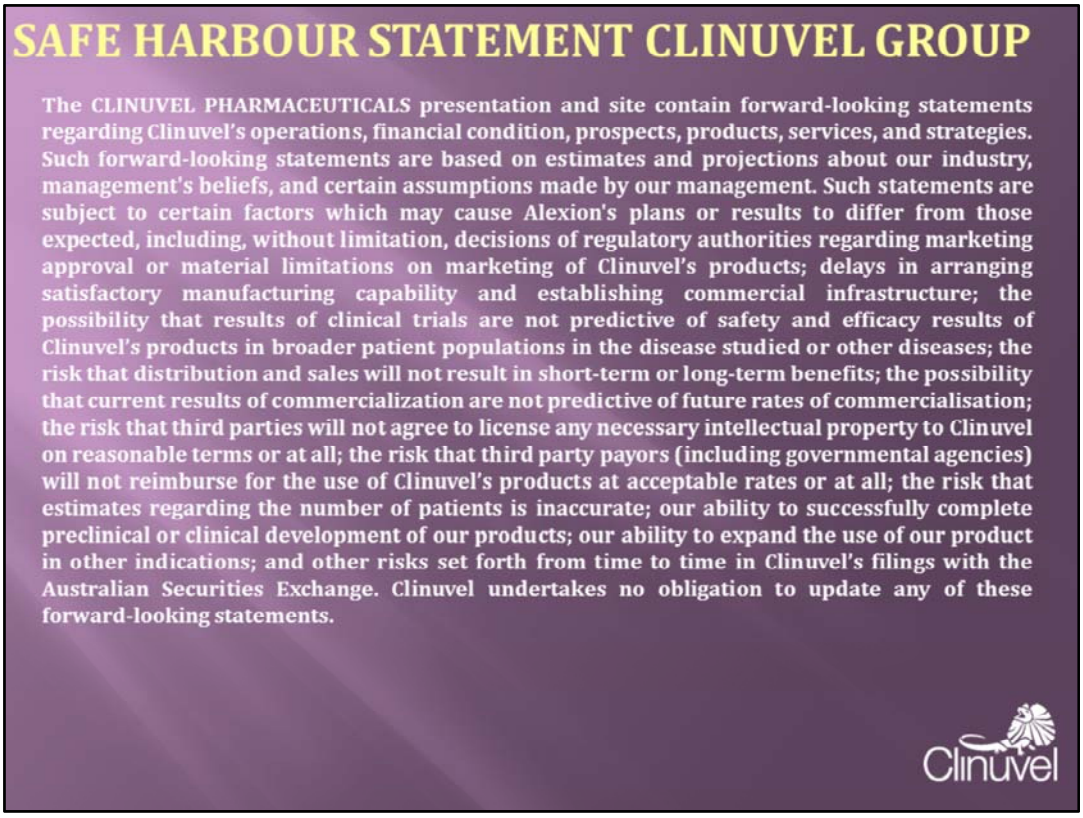


In line with European Guidelines on Medical Advertising and UK Advertising Standards for Medicinal Products, Clinuvel will not discuss the profile of the product SCENESSE® (afamelanotide 16mg) during this meeting. The product is approved to prevent phototoxicity in adult erythropoietic protoporphyria (EPP) patients. Information on the product can be found on Clinuvel's website at www.Clinuvel.com. Today's invitation is appreciated and is ahead of the launch of SCENESSE® in Europe.

The distribution of SCENESSE® as a first-in-class product.

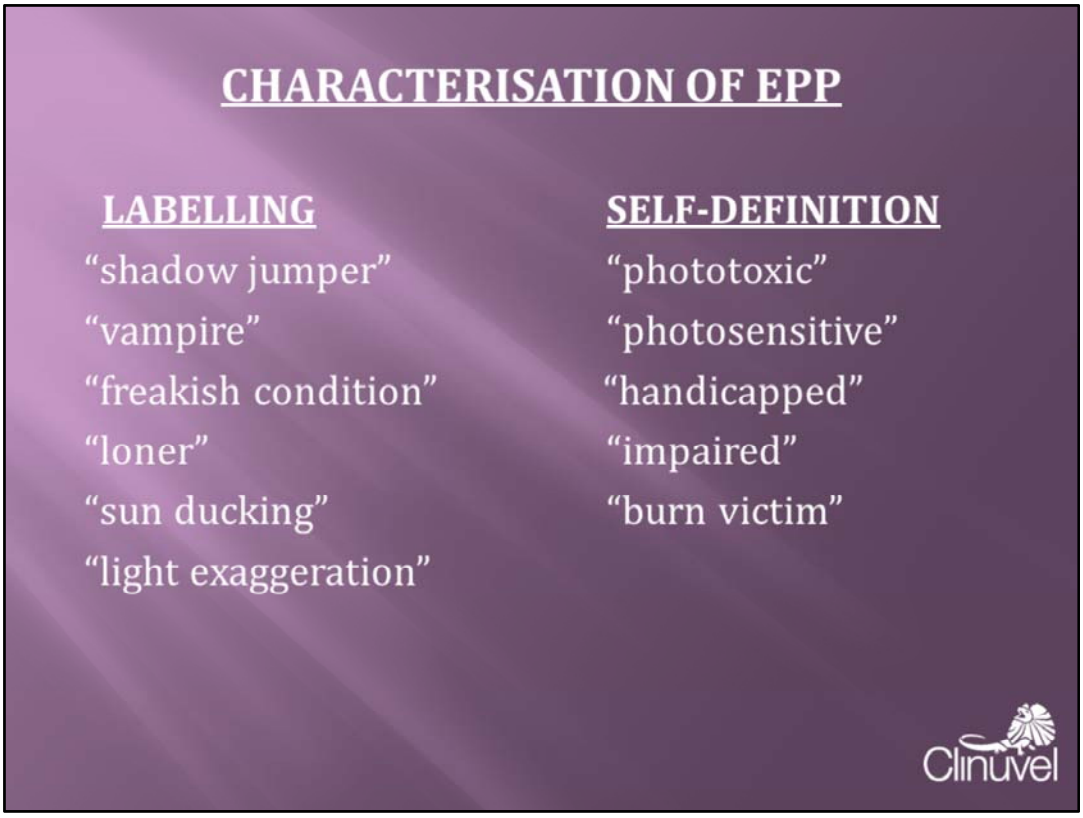
There are a number of challenges in years to come, one of these is the perception that the product could be used off-label; Clinuvel will do its utmost to avoid this. Regulatory concerns centre around this aspect.



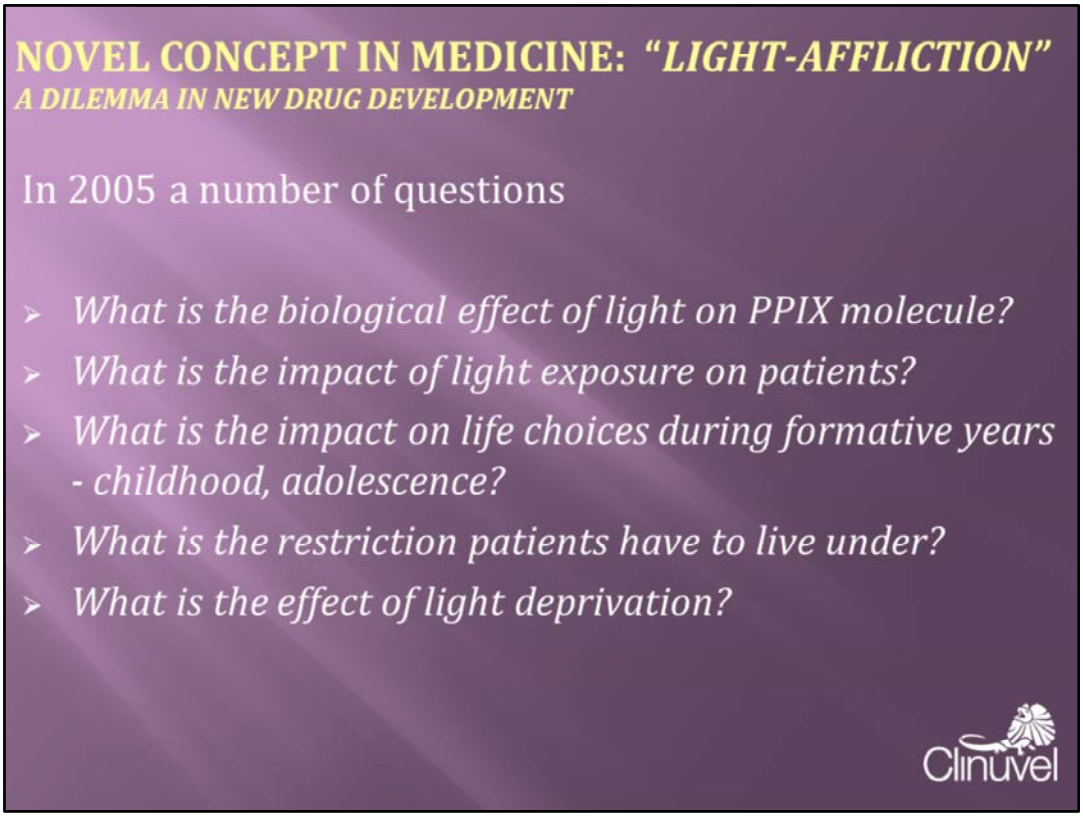
The possible forward looking statements in this discussion are not aimed at inviting or soliciting interest in the company.

Today's discussion points are relevant to physicians, experts in the treatment of the disease, and EPP patients and their families.

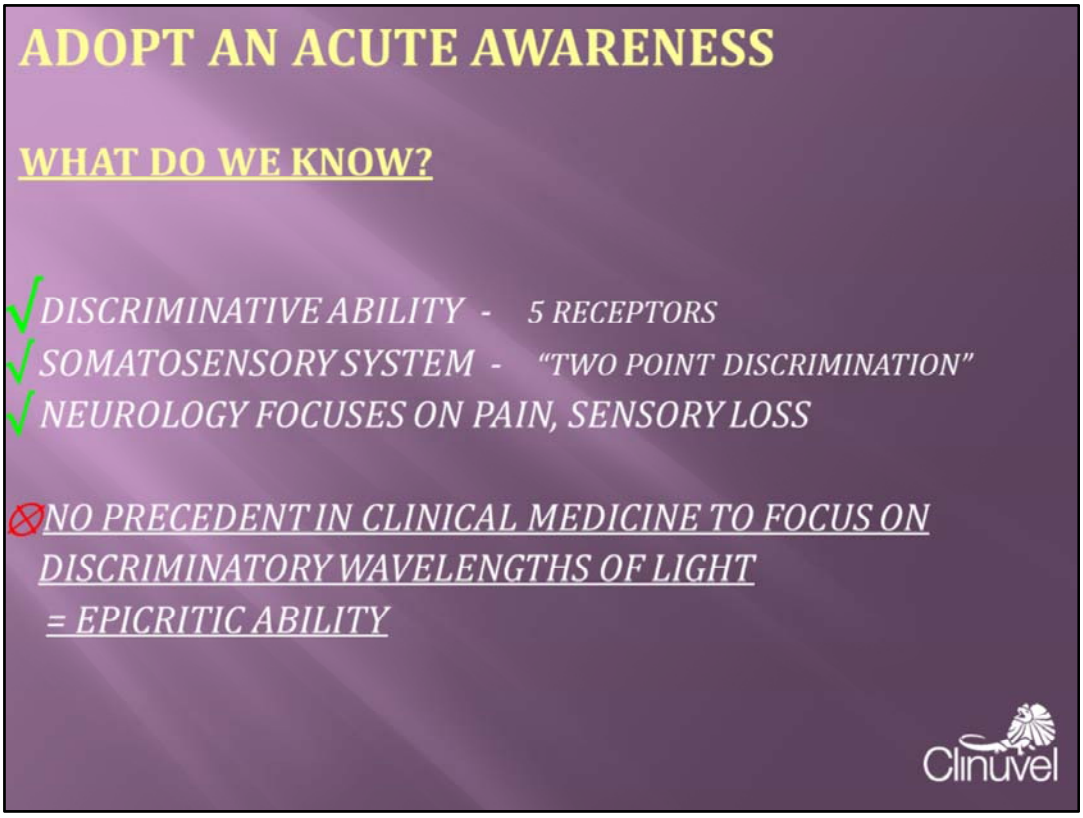
The first discussion point is aimed at characterisation of the disorder.



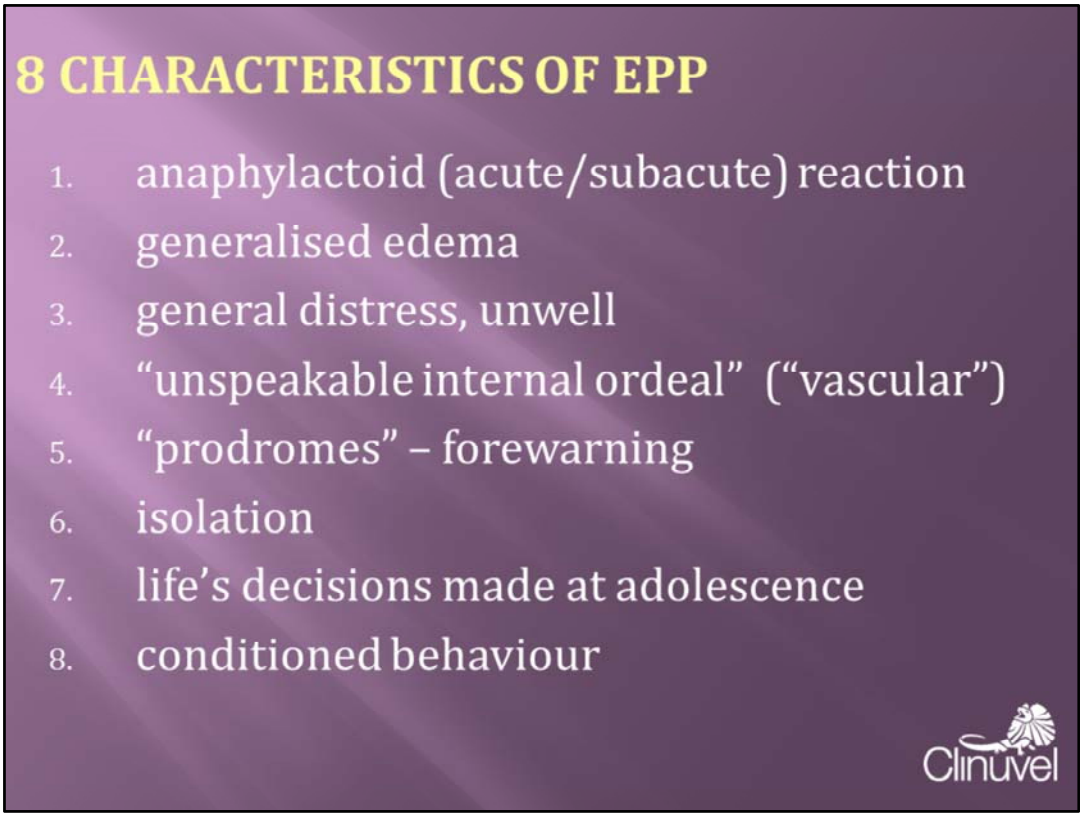
The stigmas patients have reported to our teams over the years are found in an abundance of letters, emails and from phone conversations (left).
The labelling of the disease by bystanders, 'outsiders', differs from the description patients seem to give themselves (right).



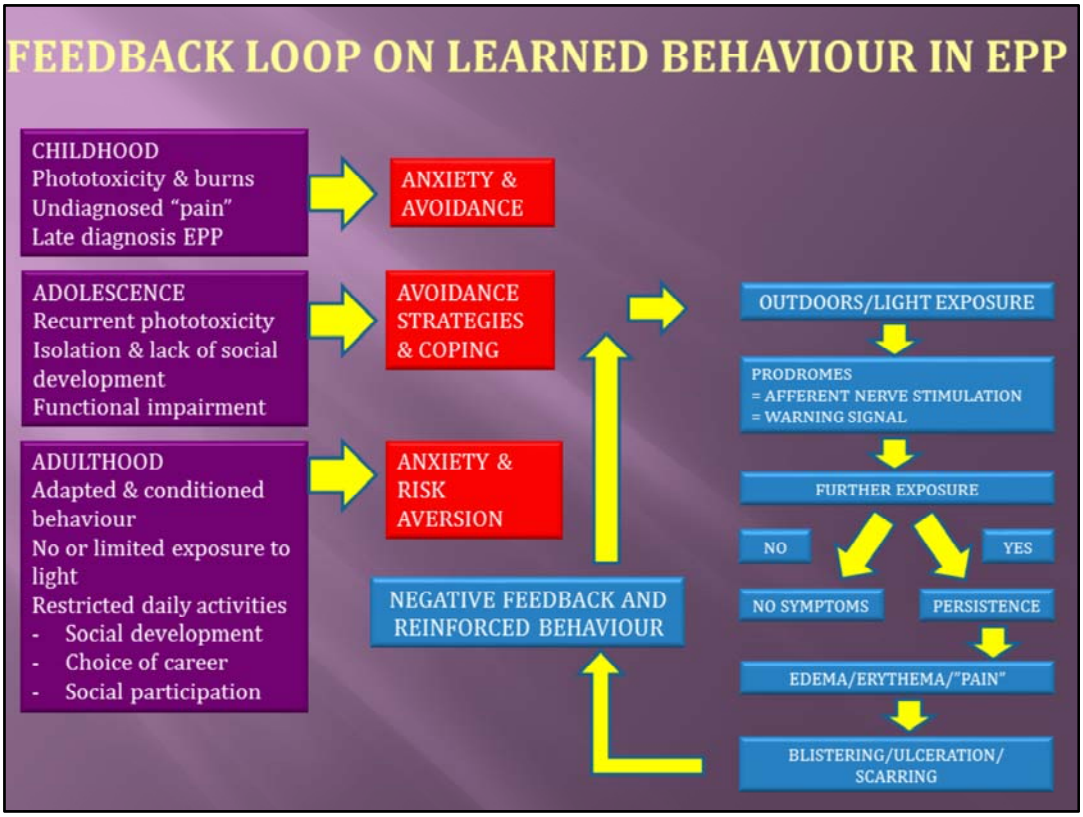
In 2005 there were a number of key questions in developing a drug for EPP, however the hypothesis of SCENESSE® was answered after the first study in 2006. The responses from patients and physicians has been stronger than expected.



In general one can not fully understand the suffering of a patient until one experiences the ordeal, symptoms and disease her/himself. This will always be the chasm between drug companies and patients. A discussion on human's discriminatory senses and especially EPP-patients' ability to discern "visible light" is led.



Over the years eight characteristics of EPP have been identified by our teams and experts, and all of them make the disease complex to evaluate.
In addition, as there are no appropriate scientific tools to measure the characteristic symptoms, the Clinuvel program led to optimum synthesis of a molecule, formulation, environment and variable clinical program.

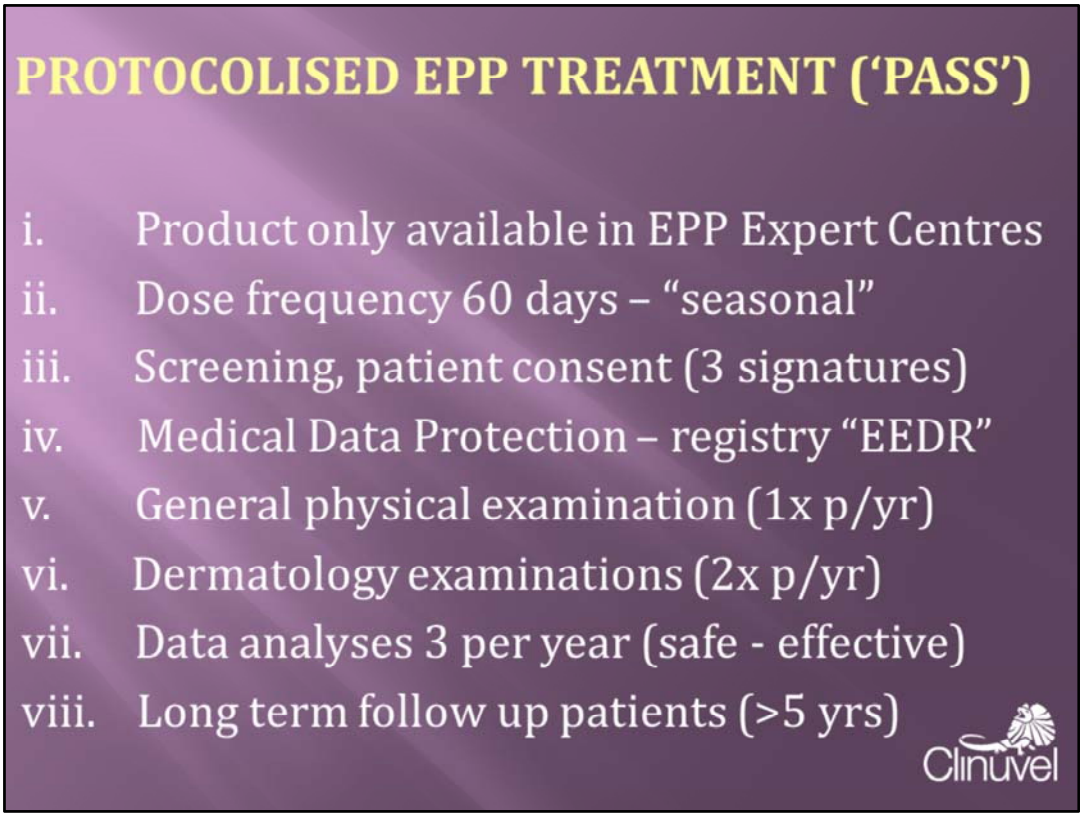


As part of the regulatory discussions and filings, this diagram was developed and is discussed today.
EPP patients are self-limiting their ability to expose due to the characteristics of the disorder. A number of behavioural components make EPP different from other light induced disorders, rare diseases or orphan diseases.

The next topic is the paediatric development.

The estimated time of development is approximately 36 months, costing millions of EUROs including product development, clinical trials, regulatory filings, follow up of patients. The regulatory views will largely determine further timelines. The successful completion of the development of the paediatric product depends on continued safety of SCENESSE® reported in adult EPP patients, captured via the European EPP Disease Registry (EEDR).

The third topic is risk management.

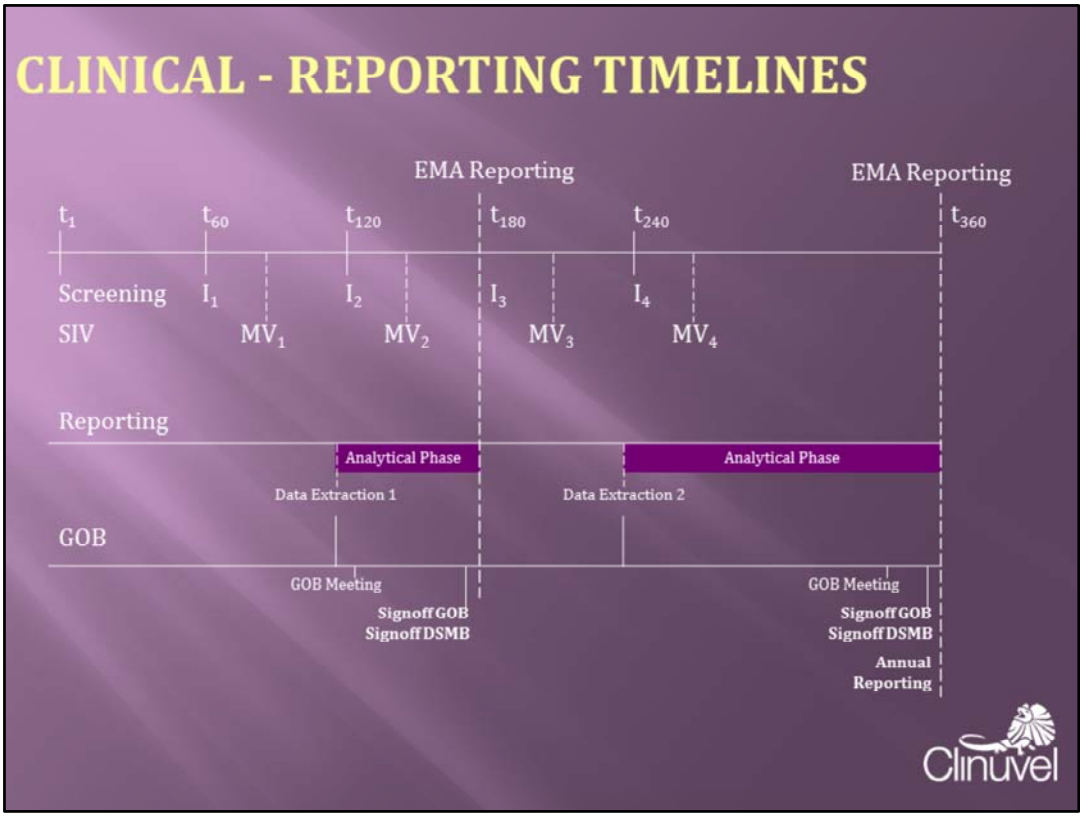


The main eight points are part of the protocolised treatment of EPP in Europe, also expected in other parts of the world.
The overall commitment for any developer of novel drugs is to emphasise PHARMACOVIGILANCE, the ability to be extra vigilant for its patients long term; Clinuvel undertakes this.

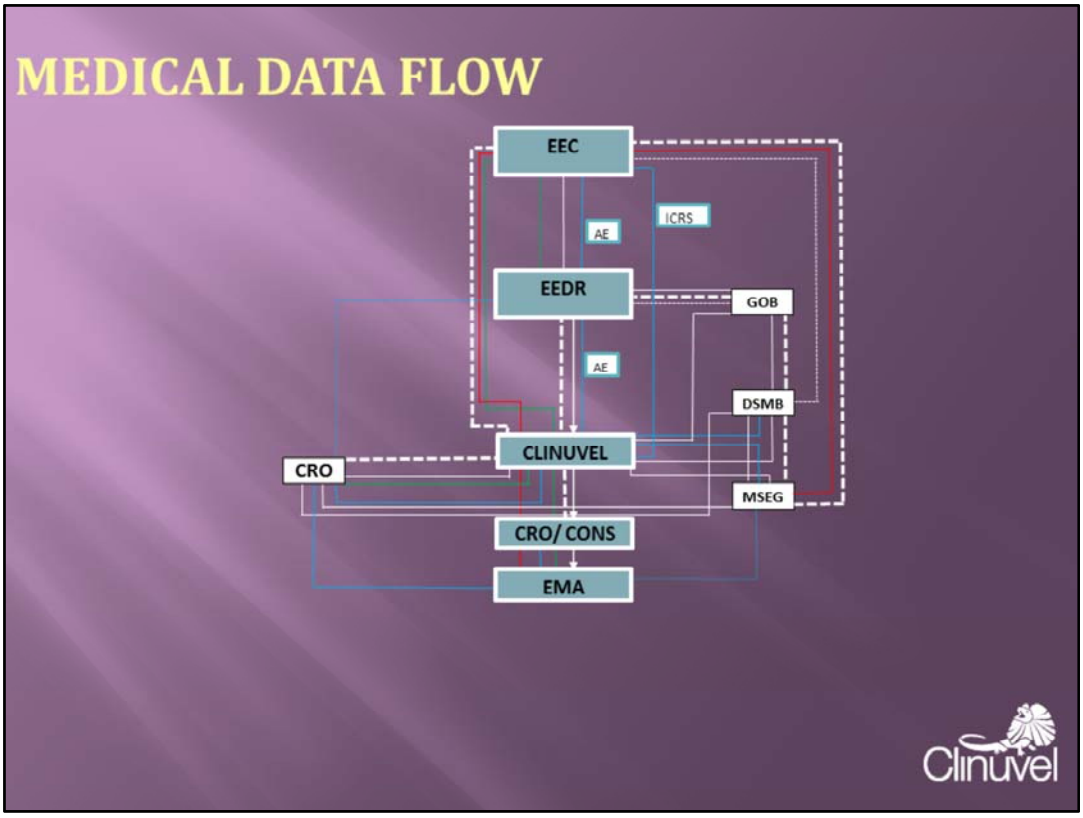
Clinuvel's initial roll-out focus is on those countries with known patient populations. The company's distribution centre is Leatherhead, UK.

Within the EU each country is assessing the product on a number of criteria, including: benefit, cost to society, number of patients expected and risk of off-label use.

Under European marketing authorisation, Clinuvel is establishing and maintaining an EPP-specific Disease Registry (EEDR). The ownership of the medical data will remain with the individual patients and reside in each medical centre, however the pseudonymised medical data related to EPP will be made available to the EEDR, and Clinuvel will have unrestricted access to these data for analytical purposes to fulfil regulatory requirements of long term follow up of patients.



Set timelines have been established by EMA for Clinuvel to report data from its European program. The timelines given here provide a sample 12 month reporting requirement.



The data flow established for pharmacovigilance is complex.
At each point of these processes, there are controls in place and all these controls form part of a pharmacovigilance management system. Each 'station' on the chart requires independent auditing of processes, proper management and adequate protection of medical data.
A number of advisory bodies, governance boards (Governance Board- GOB; Data Safety Monitoring Board- DSMB; Melanocyte Signalling Expert Group- MSEG) and third party auditors work around the clock as part of pharmacovigilance with SCENESSE®. This complex system is compulsory and aims to protect safety of patients long term.

A summary is provided.

SEEING AND OBSERVING ARE DISTINCT
IT REQUIRES DECADES TO FULLY
'UNDERSTAND' EPP

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EPP PATIENTS ARE CONTINUOUSLY WEIGHING UP

EXPOSURE VERSUS ISOLATION

RISK VERSUS CONSEQUENCES

SHADE VERSUS LIGHT

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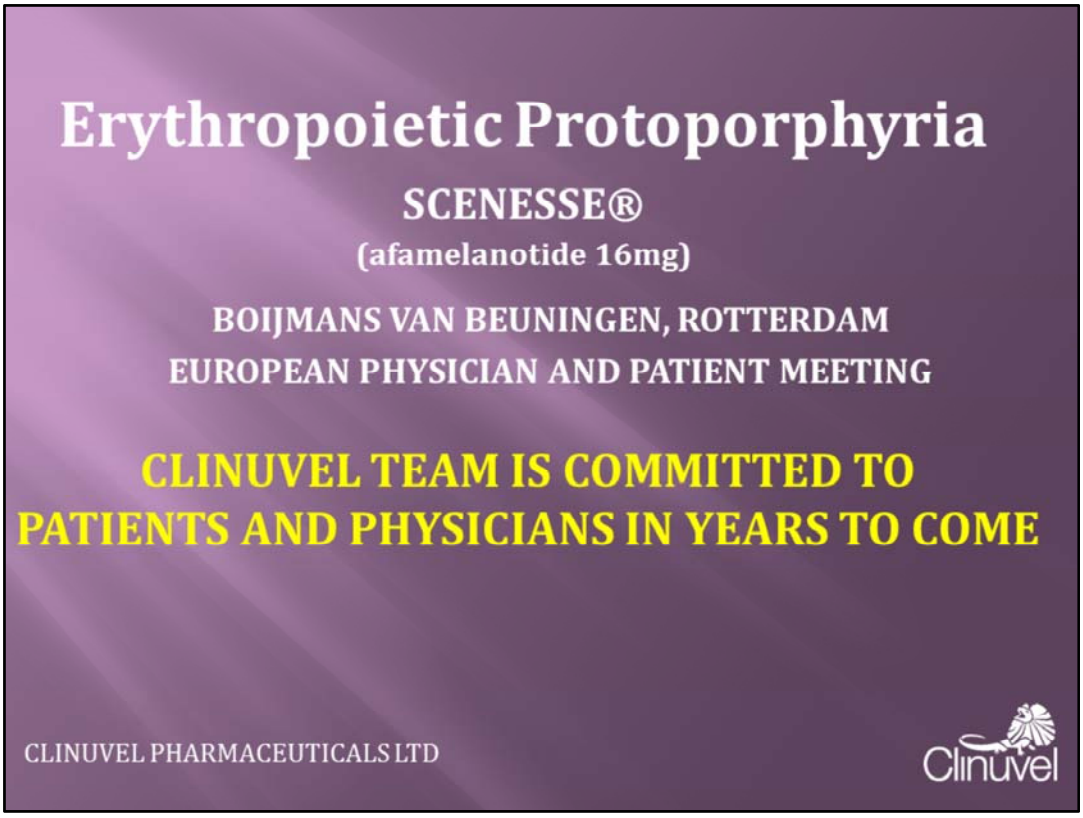
In the renaissance artists were trying to capture light in shadows on canvas. Clinuvel hopes to provide light for EPP patients who have led a life on the fringe and in darkness.

Clinuvel has devoted more than a decade to one drug in one disorder, the response of patients and physicians has made this journey worthwhile.



Thank you for the invitation.