Communiqué III, 2020 – 19 May 2020

Dear shareholders, friends,

The extraordinary times in which we are living have affected all continents. Each life lost has been one too many. I cannot express enough empathy to our Italian medical colleagues, patients and families battling it out with the tragedy. The virus has affected all corners of the world and has not spared Italy, specifically the regions of Lombardia, Lazio and Emilio Romana, where we closely work with expert physicians who facilitate treatment for our patients.

The world was ill prepared for a pandemic, although we had had ample warnings the past decade. If one is at all able to discern a glimmer of hope in these dark times, it is the universal appreciation for healthcare workers on the frontline, nurses and physicians. I believe these professionals have shown how we all are reliant on healthcare when one least expects the need for help from others, whereby hospital workers themselves are endangering their lives every day. Thus far, more than four million people have tested positive for COVID-19 and we have a fair way to go before we reach a steady state.

As CLINUVEL has entered the US and China, we turn our heightened attention to macroeconomic shifts in the two largest economies. The world is seeing a near-limitless intervention from central banks and governments with the ultimate goal of keeping economies liquid. The FOMC reacted reasonably swift with its bond buying program. US Congress have led the advanced countries by initiating economic stimulus and, altogether, the US released more than $6 trillion dollars. Australia is not far behind in relative terms, with 16% of GDP in stimulus. President Trump has not ruled out further economic aid in the next quarter which eventually will need support from the House. By providing helicopter money to the people in the form of stimulus checks and short-term loans to small and medium businesses, the US and Australian administrations are trying to build a bridge to those who need it most. The US Department of Labour released the unemployment figures (8 May) estimated at 14.7%; with more than 33 million US jobs lost in eight weeks, this virus is directly affecting large swathes of society. In some countries a moratorium has been imposed on furloughing workers as companies spun into difficulties, but the need to rationalise one's fixed business costs becomes unavoidable. In Germany, unemployment rose mildly in comparison, to 3.9% in April, but with provisions in place to shorten employment ("Kurzarbeit") and payment of up to 60% of regular wages to save jobs overall.

It is apparent from the economic indices that negative growth in the US, Australia and some European countries forebode longer-term consequences of the pandemic. We can rely on some of the learnings from the Great Recession which showed that the loss of productivity reverberates for many years to come. Governments of advanced economies strapped for cash will need to increase investment in technology, infrastructure and sciences in order to not see the knowledge gap with Asia diverge even more. On the positive but bleak side of the tragedy unfolding, we have at least seen regulations being relaxed and authorities willing to assist to keep processes fluid.

Although equity markets have rebounded remarkably quickly, we believe that volatility will continue for quite some time. At CLINUVEL, we anticipate further contractions as part of global incertitude. To transit through these times, I believe we need to maintain a resilient balance sheet. I intimated before that there will be an ever-lasting tension between deciding on the quantum of reserves held and reinvestment of capital in pharma projects, however I fervently believe that liquidity provides optionality for our sector to withstand systemic risk. The experience acquired during previous crises has taught that maintaining liquid assets eventually results in value recognition. In time, institutional investors will make a distinction

per sector between those distressed and those going concerns without further equity required. The corollary is that a strong financial status assuages anxiety from employees, shareholders and patients of an operation at risk. The consequence of such market perception alone would cause irreversible damage to the value of a company which is just in the flow of distributing its product in two markets. Therefore, we steer clear from the vicinity of economic anguish.

Overall, the pharmaceutical industry has felt the immediate effects of the global threat with the slowing of supply chains, and hospital treatments being cancelled and limited to the most essential (non-elective) and acute care. While some medical device manufacturers have seized the opportunity by increasing supply of masks, protective equipment and ventilators, others have offered their pharmaceutical products for larger clinical trials hoping to see a positive effect on the viral load and other parameters.

The interval has provided CLINUVEL with time to regroup in anticipation of significantly changing business conditions. We hold a broad consciousness that we must adapt to a new environment which requires flexibility and, certainly, a different mode of operating. CLINUVEL has faced quite some head winds over the years; the Company has withstood two economic crises and each time, due to pliability of minds, we were able to circumnavigate. While each sector will have to come to terms with the fact that lost time and opportunities cannot be made up, there are some positives to be found. Through these times, I wish to see to see our teams working at proxy providing a maximum output, work longer and more concentrated to overcompensate for the lack of face to face cross-functional activities. These circumstances call for exceptional performance and creativity: do more with less.

In this strenuous era, I tend to revert to minute analyses of all optimal versus suboptimal historical decisions and the upshot is overwhelmingly positive, providing me full confidence that our staff are best positioned to adapt to radical uncertainty. In undertaking a critical analysis of the chronicled directions taken by our teams, it has been delineated that decisions were mostly determinative in nature when solutions were imminently demanded from us. Going forward similar decisions are expected.

Further, I witness that ingrained processes within CLINUVEL have led to a higher factor productivity coming from integration and repetition. Less capital seems to be required to achieve contiguous objectives due to efficiencies and scalability of some of our processes, and funds can be reallocated to new projects. Dictated by the global restrictions, resourcefulness means operating at distance, calculated travel reduced to necessity and therefore fewer in-person interactions with hospitals, regulatory authorities, legal services and key suppliers. New ways of remote communication have dominated our daily work, and thus far I can state that it has not affected the quality of output.

Above all, we do not wish our staff to be exposed to higher contact risk and hence new times require us to find perspicacious ways to attain progress. As our R&D facilities in Singapore are temporarily suspended by the government, our staff are compelled to model research activities online and pleasingly progress is being made. Given the economic history of Singapore, I am absolute that it will be one of the first countries handling the viral threat of recurrence, coined the third wave, while putting in place national measures to protect its population to sensibly restarting its economy. Our new laboratories are being built and we now expect these to complete by August.

Naturally, we receive questions as to the distributive consequences of the pandemic. The last quarter, we had not seen a significant slow-down in product uptake, but only when full data sets on the European supply are analysed by calendar year-end will we be able to assess the true impact of COVID.

UPDATE ON US DISTRIBUTION SCENESSE®

In October 2019, we made public our intention to initiate US distribution by Q4 2020. Due to the time and work we had put in the past two years in preparing US insurers ahead of the launch, our teams were able to start ahead of the forecast. As released on 16 April, more than thirty US insurers have agreed to reimburse SCENESSE® (afamelanotide), six months ahead of our internal forecast. Since then

we have seen an expansion of payors and the first state insurance covering patients under Medicaid.[1]

As soon as the threat of viral infections eases off, we will train and accredit more Specialty Centers enabling optimum access to US patients diagnosed with erythropoietic protoporphyria (EPP). The clinical demand for SCENESSE® surpasses our expectations so far, the news reached us that more EPP patients are flying from all parts of the US to seek treatment.

Our approach to risk in managing the clinical supply in the US is symmetrical to the one already set up in the European Union, where a pharmacovigilance system was established in 2014. At present, we are awaiting the FDA's final review of the US post-marketing plan for SCENESSE®. In the meantime, we distribute according to the EU risk management plan. This focus on risk management is found within all divisions and cross-functional teams within the Company.

What started off as an ideology has now become part of our risk management, namely the measures in place to ensure that no off-label use of SCENESSE® can take place. As per agreement with FDA (and European Medicines Agency; EMA), off-label use of afamelanotide will not be allowed under the controlled-distribution system established by CLINUVEL.

Naturally, we ask ourselves whether ideology and commercial reality are compatible and in the best interest of the owners of the company? I recently learned first-hand the effect our policy has had on decision makers, EMA and national insurances, who both had expressed scepticism in 2014. In a dialogue with the EMA's Committee for Medicinal Products for Human Use (CHMP) the compliance of our company was commented as unexpected and pleasantly conforming with commitments made six years ago. After the lifting of the COVID restrictions, we will meet with the EMA in Amsterdam to evaluate four years of commercial supply of SCENESSE® within the EEA, and it will be a pleasure to discuss the Risk Management Plan and lack of off-label use as per our agreement. I conclude that the EMA's ongoing willingness to assist us must stem from the covenants respected by our teams. Paradoxically, in living up to certain restrictive undertakings substantial value can be found and created, thus the approach is no longer just an ideology.

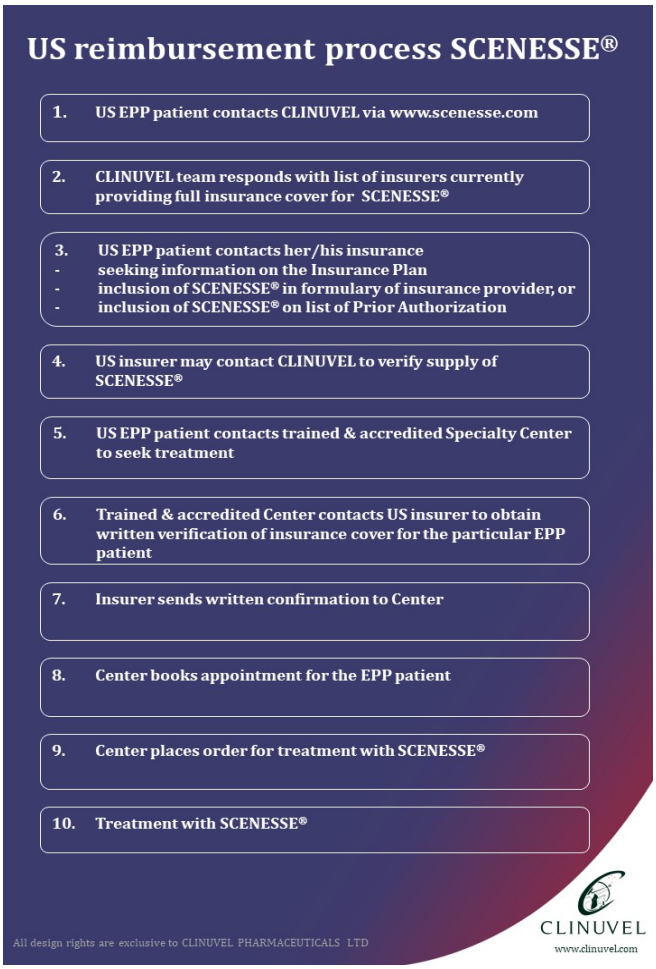


Figure 1 Flow diagram of current US treatment access 5

Differentiating from the pack by operating in this manner is already yielding economic results.

The perspective of insurers is equally relevant. When our teams present and discuss the introduction of SCENESSE® to US formularies and national orphan drug lists, it is only logical that these organisations want to know the foreseeable dollar impact of a new pharmaceutical on their annual budget. Rather than taking a moral high ground (in entering an agreement with insurance companies there is absolutely no room for moral hazard), the discussions on the potential of off-label use impact allocation decisions and therefore the willingness to reimburse SCENESSE®. For a pharmaceutical company able to provide a precise annual budget impact helps greatly in obtaining the Average Wholesale Price or Drug Price as reflected in value for money. As part of the continuity in reimbursement under Prior Authorization and standard of care on individual formularies, CLINUVEL is expected to confidentially disclose to US payors how many patients can be expected per

catchment area and the number of treatments per annum. A prospective favourable outcome can only be obtained if one is candid in one's risk assessment of off-label use.

The point is that allowing off-label use would not only contravene the "firm understanding" between pharmaceutical company and insurer, but also the ability to monitor patients long term. Exceeding budget allocations year on year as made by insurers and national agencies by making a drug available outside its label swiftly erodes entrusted confidence and makes the discussions for the subsequent years next to impossible.

Without having firm evidence yet, I believe the progress in distribution made by our teams in the US and Europe stems from the fact that insurers have built faith in our ability to live up to agreements on pricing. I have nothing but praise for our senior managers in charge.

AUSTRALIAN TGA SCIENTIFIC REVIEW

The progress of the scientific review by the Australian Therapeutic Goods Administration (TGA) remains as reported previously. In **figure 2** we demonstrate the overall timelines and processes. Under the Priority Review Pathway a critical appraisal is expected in the next few months. Global regulatory authorities place specific emphases on a technical dossier during their appraisal and the TGA's approach differs to that from the FDA and EMA.

The interaction between the Australian agency and Company is expected to continue until the very end of the review. The emphasis thus far has been to ascertain whether SCENESSE®, as part of therapeutic goods supplied in Australia, meets acceptable standards of quality, safety and clinical benefit.

Overall, the TGA will need to assess whether the evidence of safety as well as efficacy in 580 EPP patients – in controlled as well as real world use – presented is proven and sustained. We expect the TGA to be able to conclude its final scientific evaluation by Q4 2020, whereby the agency has the option to call a drug evaluation committee in the case it needs further advice about a new product.

In parallel, interactions with the Pharmaceutical Benefit Scheme (PBS) are being prepared to exchange information on risk, benefit and budget impact in Australia. The aim is to assess whether SCENESSE® can become listed on the PBS in Australia.

For a pharmacy drug, patients generally have a Safety Net threshold (A$1,486.80 for general patients in 2020) per calendar year, meaning that patients have a co-payment obligation for further PBS prescriptions.

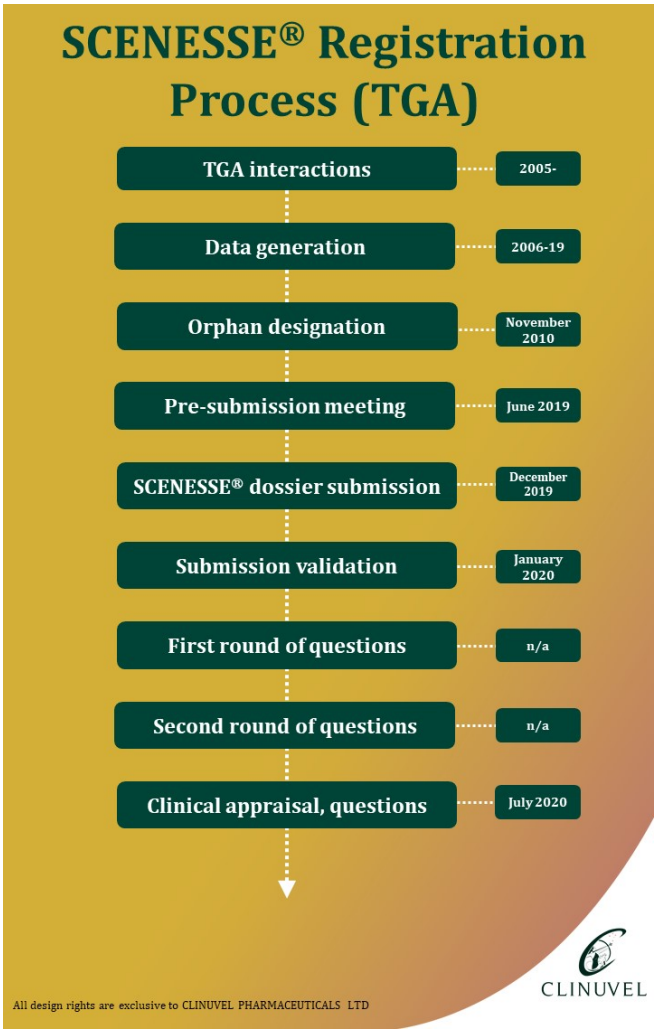


Figure 2 TGA pathway and approximate timelines

In the case of SCENESSE® it is expected that the drug will be made available exclusively through outpatients' departments of specialty centres since it will be administered by specialists only.

The process of review is led by the Pharmaceutical Benefits Advisory Committee (PBAC) and it is through a major submission that we start the pathway to include SCENESSE® in the PBS list. More information will be forthcoming as the TGA procedure advances.

VITILIGO IN NORTH AMERICA

On 29 April, a Type C meeting was held with the FDA to discuss the path to make SCENESSE® available under a supplemental New Drug Application (sNDA). Since there is no FDA approved therapy for vitiligo (lack of comparables), we judged it prudent to request a Type C (guidance) meeting and engage the FDA in a discussion on future label and use of the drug under real-life conditions.

The sNDA pathway allows for changes to the label of an approved drug, including adding new clinical indications, doses or formulations. A discussion with the FDA prior to advancing a North American program is not obligatory, but very much part of good practice as it provides support for study design and a future product label granted by the respective Division.

Our regulatory team is now engaging in final protocol exchanges with the FDA with the aim of reaching agreement on a number of issues counting towards approval of SCENESSE® (pending further efficacy). Although the FDA requests that the content of these discussions remain confidential, we are able to provide some clarity on general items which centre around introducing a novel solution for a disease devoid of effective therapy (unmet medical need):

a. a minimal clinical effect to justify systemic treatment;
b. agreement on product label (if the product proves safe and effective);
c. differentiation between treatment groups (most clinically affected versus less impacted patients);
d. objective viewpoints from key experts in vitiligo; and
e. prescription, distribution and use of the product under real-life conditions.

The five points call for some clarification.

The reported prevalence of vitiligo varies globally, but consensus is that the disease affects between 0.5-2% of the US population. The exact disease

Figure 3 Regulatory pathway for afamelanotide in vitiligo

mechanism of action is not fully elucidated, but it is generally accepted that the loss of viable pigment producing cells (melanocytes) is due to an autoimmune component, causing incremental loss of pigmentation in patches or "lesions". Patients experience gradual disappearance of pigment, sometimes symmetrically, sometimes per affected body part. In particular in those patients with darker skin types, an accompanying sense of loss of identity results in social withdrawal and a desperate attempt to mask the loss of pigment.

Our sector has made a number of attempts in the past 30 years to find treatments for vitiligo. All therapies available to a dermatologist are used off-label, meaning these therapies had been approved for other disorders but 'tried' in vitiligo by virtue of not having better alternatives. According to the global experts all of these treatments are poor and not satisfactory. At the same time, one needs to distinguish severity of vitiligo in patients with a dark complexion, where the contrast of pigment loss is the starkest. Certainly, one must consider the overall benefit to patients of treatment, when the disease affects visible or intimate parts such head and neck including face, hands, feet, lower legs and even the genital areas.

There is a common framework among scientists, academic researchers and clinicians that an optimal treatment would need to be endogenous, that is simultaneously activating all pigment producing cells (melanocytes) of the body. Spray-on techniques, transplantation through skin surgery and grafting are not really viable treatment options for facial or large areas of vitiligo. The worldwide attention currently is either for a pharmaceutical product to re-activate melanocytes or prevent the immune system from destroying the melanocytes.

As a juxtaposed but certainly not unimportant objective, CLINUVEL sees a clear social mandate in our work to assist those patients of colour who are most severely affected by a condition and lack therapeutic alternatives (unmet need). At this time there are no approved pharmaceutical treatments for vitiligo and the accepted standard of phototherapy – narrowband ultraviolet B or NB-UVB – requires clinical visits two or three times per week for 12 to 18 months to see some therapeutic response. Yet the treatment is notoriously inconsistent, placing inordinate burden on patients and healthcare providers. In more than one way, the lapse of time has assisted in the decision to advance SCENESSE® by helping determine whether the drug would occupy the position of treatment of vitiligo or not. Based on unbiased expert opinions, afamelanotide is highly needed in vitiligo.

Whereas the pathogenesis (origin) in vitiligo remains part of much contention, it is well accepted that once mature melanocytes are affected by the disease, the production of pigment (eumelanin) is minimal to zero (auto-destruction).

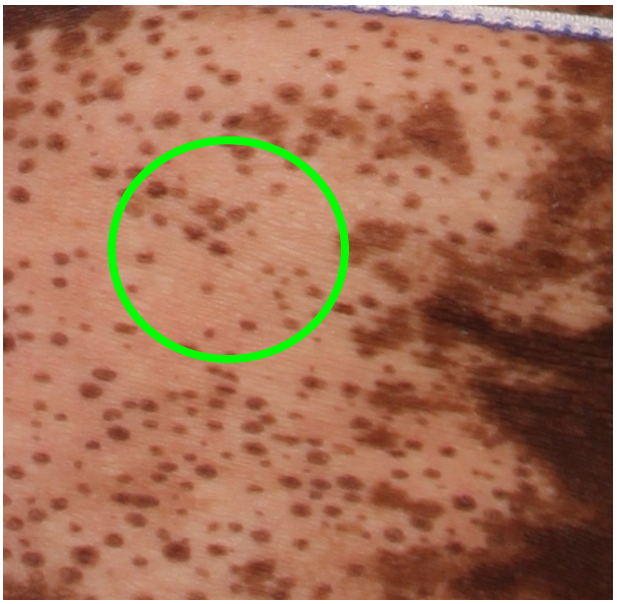


Figure 4 Follicular repigmentation following afamelanotide 16 mg
Stage one: start of follicular repigmentation expressed as singular islands (within encircled area)

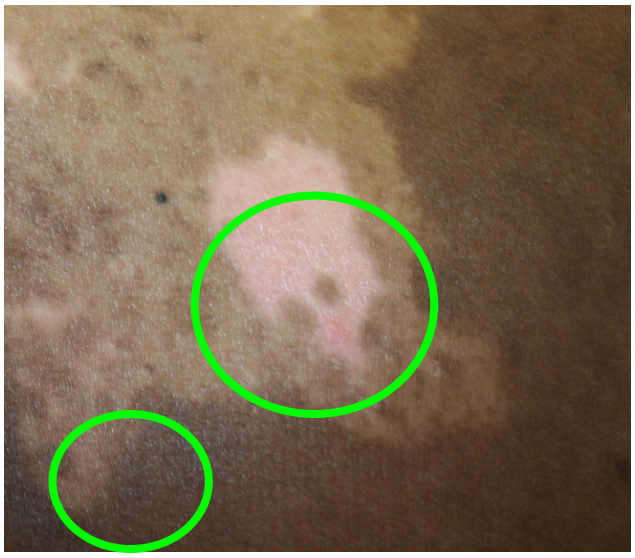


Figure 5 Follicular repigmentation following afamelanotide 16 mg
Stage 2: conflation of follicular islands repigmentation expressed as singular islands (larger circle)
Stage 3: Integration of epidermal pigment (smaller circle)

The challenge and scientific opportunity CLINUVEL seized was to target the activation of immature melanocyte pre-cursors (melanoblasts) residing in a reservoir (niche) sitting next to the hair follicle in the dermis. From here onwards, it is understandable that accelerating the development of these precursors to fully mature melanocytes is a desirable pathway to replenish the "damaged" melanocytes which have succumbed to the disease.

In the CUV102 and CUV103 studies, CLINUVEL found that the treatment regimen of SCENESSE® in combination with NB-UVB can accelerate the maturation of the melanoblasts, eventually leading to the desired follicular repigmentation. Follicular repigmentation is the preferred effect a clinician wants to see as it indicates the repopulation of pigment producing cells arising from deeper dermal layers. The mechanism of action of afamelanotide remains essential in our endeavour to introduce innovation in vitiligo. The melanocyte activation is one part, but the molecule has equally strong anti-oxidative properties.

The first indices of follicular repigmentation are seen as small "islands" of *de novo concentric pigmentation*, expressed as dark speckled fields within in the depigmented vitiliginous lesion (see **figure 4** encircled). The second stage is when the follicular islands merge with the periphery of the pigmented areas, the conflation of follicular and peripheral pigment marks the start of full repigmentation (see **figure 5,** larger circle). The third and last stage is when the conflated areas adopt the same pigment colour as the surrounding skin, that is full pigmentary integration (see **figure 5,** smaller circle).

As we have published in our Vitiligo Communiqués in 2018 and 2019 (see Communiqué I, II and III), the quality of pigmentation differs per ethnic population. In general, one can say that the size of the melanin complexes in Caucasians is seen as smaller particles ("dust") than in darker skin types such as seen in African Americans, microscopically characterised as larger ("granules") particles. Patients of darker complexion not only have a greater ability to re-generate eumelanin but also larger size eumelanin complexes. Despite the fact that the prevalence of vitiligo among darker skin patients is equivalent to that reported globally in all skin types, clearly the impact on patients of colour is the highest and constitutes the highest unmet need in the disorder.

We shall provide further updates on the program as it emerges.

DNA REPAIR

The current knowledge on DNA damage and response is largely based on data generated in the specialisms of radiotherapy, nuclear medicine and physics. In the field of radiotherapy, DNA damage response (DDR) proteins present as viable targets to increase the effects of radiotherapy. DDR has become one of the determinants of cancer cell responses to chemo- and radiotherapy, most of which cause DNA damage directly or indirectly.

UV radiation causes damage to skin cells, and as a response human skin cells develop photoproducts – UV signature mutations – cyclobutene pyrimidine dimers (CPDs), 6-4 Photoproducts (6-4 PPs) and Dewar pyrimidines (Tpt3s). It is known that patients of light skin complexion and with certain mutations of the melanocortin-1 receptor (MC1R) are at far greater risk of these photoproducts, as well as subsequent mutations (skin cancer; readers are encouraged to review the Scientific Communiqués on our website).

Grosso modo, DNA damage is expressed as single-strand damage (single-strand breaks, base damage, abasic sites) repaired by nucleotide excision repair

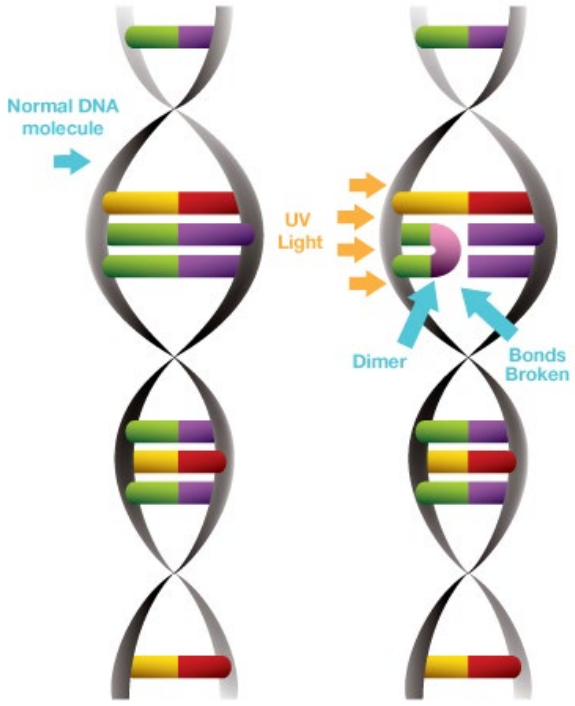


Figure 6 Single strand break in DNA helix following UV radiation

(NER) and double-strands mutations by a set of base excision repair (BER) pathways.

DNA repair systems have been the object of studies around the globe as we have to deal with the constant threat of DNA damage from exogenous sources (UV light, low-level background ionising radiation, genotoxic chemicals) and from endogenous radical oxygen species. One needs to realise that, for the most part, DNA damage from these sources is widely dispersed, and under normal circumstances repair pathways are highly efficient. These homeostatic (balance restoring) mechanisms prevents the human body from incurring skin cancers after each session of sun/UV exposure.

Within each cell a great number of proteins and genes come to expression. For instance, down the cellular pathways ATM and ATR are master regulators of DNA damage, so called checkpoints, but also tumor suppressor genes and other proteins play an important role(for further information we refer to the Scientific Communiqués).

CLINUVEL's objectives of the DNA repair program are to evaluate the possible effects of the use of afamelanotide in patients who suffer skin damage following UV exposure.

The preparation of the first human pilot study (CUV150) in DNA repair is awaiting approval from local regulatory and ethics authorities due to the COVID slow down, however we are optimistic that we will be able to start soon with the first dosing to patients.

PUBLIC AND INVESTOR RELATIONS

As our Chairman outlined in his 8 May letter to shareholders, digitalisation is key to business efficiency. The COVID-19 pandemic stressed the necessity to further our technological arsenal of communications, and the impact on our planned IR participation in conferences around the world this year. CLINUVEL is embracing the technological channels that are readily available to communicate effectively and will invest in further means to optimize connections that are so critical in business.

These channels are equally of importance to spread CLINUVEL's story among a wider audience. With our shareholder register diversification geographically – particularly across Australia, Europe and the US – the modus operandi of investor relations and communications personnel has extended from frequent audio to video teleconferences, developed from physical to virtual participation in conferences, and stepped-up in the frequency of communication through various channels. The next few days, we shall participate in two virtual global healthcare teleconferences – UBS on 18-20 May and Jefferies on 2-4 June – which previously would have required personnel to travel to New York to present.

We welcome several new shareholders, both private individuals and institutions, who have recently invested in CUV. It is also seen that some longstanding shareholders have increased their stake in CUV in recent months. Some institutional shareholders have commented that the frequency and content of our communications has enabled their investment decision in CUV.

Month	Planned Events
January	JPM Healthcare Conference, San Francisco
March	Jefferies Healthcare Summit, Zurich
	Photodermatology Society Meeting, Denver
	Skin of Colour Society Symposium, Denver
	American Academy Dermatology Meeting, Denver – CANCELLED
	23rd Asia Pacific Pharma Congress, Singapore – POSTPONED
May	UBS Healthcare Conference, virtual
	UV & Skin Cancer Prevention Conference, Mechelen, Belgium CANCELLED
	Congress Italian Society of Dermatology and Venereology, Florence CANCELLED
June	Jefferies Healthcare Conference, virtual
	American Society for Photobiology Meeting, Chicago
July	British Assoc. of Dermatologists, virtual
September	ESPD Photodermatology Day (TBC)
November	Jefferies Healthcare Conference, London (TBC)

We acknowledge the first language of many shareholders is not English and we are committed to communicate directly with them in their language. We recently communicated the commencement of our collaboration agreement with Winhealth Pharma through social media in Mandarin and, continuing an initiative commenced earlier last year, our German-speaking shareholders will shortly receive a translation of this communiqué in German. We will progress this trend of frequency and diversity of multi-lingual communication in the future.

SUMMARY

On 31 January and 28 April, the company published its quarterly reports (quarters ending 31 December 2019 and 30 March 2020, respectively), with half year results published on 26 February. Since 2016, we have been on a growth trajectory, and the question answered at the end of July will be which impact, if any, COVID-19 may have had on CLINUVEL's Final Year 2020 results (30 June).

As the financials support the expansion of CLINUVEL, much of the preparatory work in the past decade is now coming to bloom. It is a true privilege to plan and see that these blueprints become reality; it makes working for this Company a unique experience.

A recent conversation with one of our new institutional shareholders centered around the wave of capital raisings seen in our sector during the viral crisis and how CLINUVEL looks at this. The Board of Directors and I view perpetual dependency on equity financing as most undesirable in our sector unless there is a compelling reason for the use of funds. The guardianship of a company's share capital does not attract much attention in financial literature, but I view this aspect as being as essential as other parts of active management.

I have talked extensively about the dilutional effect of frequent capital raisings and the attention placed on establishing a stable registry. CLINUVEL's fiscal management was aimed from day one to achieve independence, and there is no reason to change this course, although no viewpoint is rigid, and we do review our position on this matter periodically.

I look at a very positive future for CLINUVEL, an expansion thrift and enthusiasm to bring all our simultaneous projects and developments to the stage of commercialisation. There is a balanced Board of Directors, a senior management team which was kept together for more than a decade, and a next generation of talent bringing new skills to the Company. The teams are brimming with confidence and energy, and against all this optimism, my role is to caution all of our staff not to let complacency creep in.

In conclusion, I am most pleased to learn that US patients who had been waiting a decade since the first US trial in EPP are finally receiving the treatment.

Although our US product label states that patients between 18 and 70 years are eligible to receive SCENESSE®, one letter from **a 71-year aged US female EPP patient** affected us all. This patient had been waiting seven years to receive the treatment after having received the active drug in our trials (CUV039). With a longer than expected FDA review, she recently discovered that she was **beyond the eligible age** to obtain the therapy and lamented her situation: she had been anticipating the moment she could live a full unrestricted life as experienced in 2012, and now that hope had vanished overnight.

I have expressed in previous NewsCommuniqués that I regard the current regulatory process to be wholly inadequate for approving innovative drugs while intellectual property rights of innovative companies are being eroded by a development timeframe of, often, more than 10 years. There are some ways to see the patent lives extended, and clearly our patent lawyers continuously work on these. In addition, the legal position of making drugs available until the age of 70 requires urgent review from both EU and US legislators since life expectancy is being pushed out in global economies.

We did not need much time to decide to make the drug available to this 71-year young female patient, even if it meant to act beyond the US label! The notion that she will be able to lead a life she had dreamed of during seven years of waiting is worth all the fights CLINUVEL has endured to arrive at our position. In this particular case we will go beyond a man-made pharmaceutical label dictating an arbitrary age-limit.

At this point in time, I thank all of the European and American patients as well as the patient associations and individual advocates. The physicians taking care of these patients have proven exceptional. Finally, to my staff and Board, my appreciation for your relentless pursuit to drive the Company forward.

Philippe Wolgen

[1]SCENESSE® (afamelanotide 16mg) is approved in the European Union as an orphan medicinal product for the prevention of

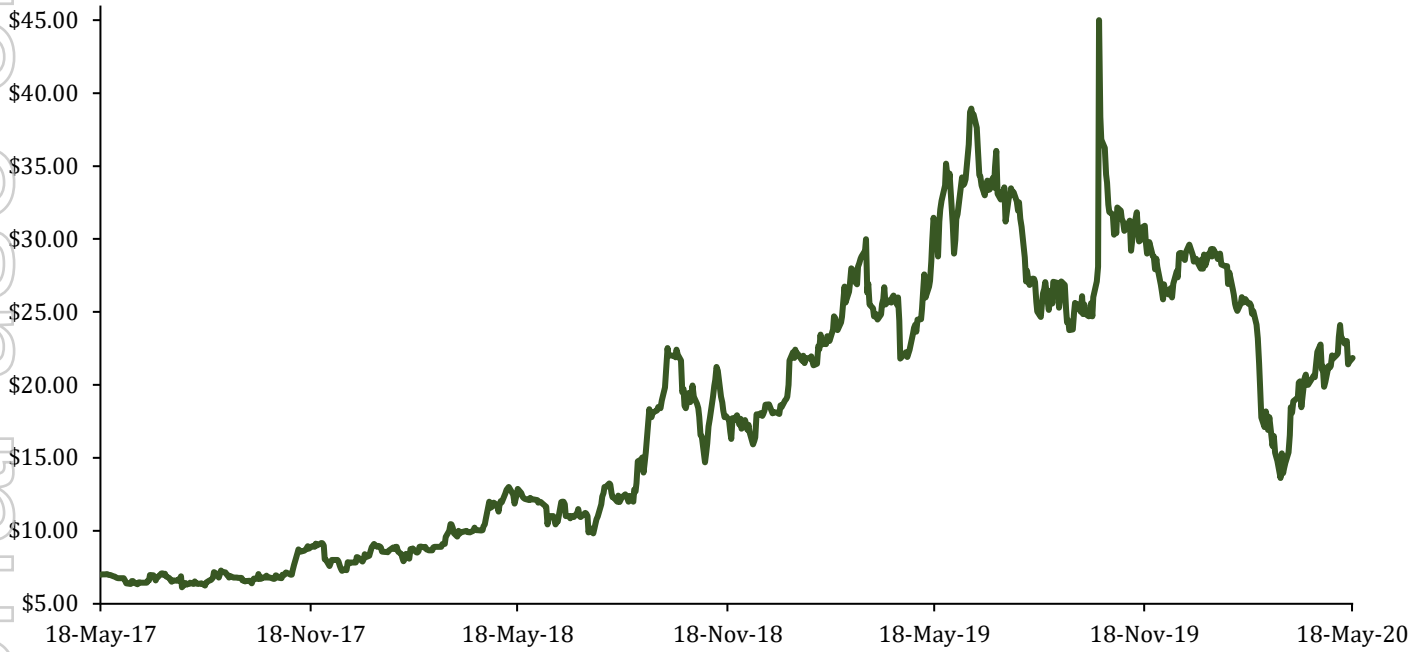
phototoxicity in adult patients with EPP. SCENESSE® is approved in the USA to increase pain free light exposure in adult EPP patients with a history of phototoxicity. Information on the product can be found on CLINUVEL's website at www.clinuvel.com.

ASX: CUV

Shares on issue	49,410,338
Fully diluted	49,563,046
Market cap (18 May 2020)	A$1.079bn

Share price

(ASX: CUV 18 May 2017 – 18 May 2020)



Authorised for ASX release by the Board of Directors of CLINUVEL PHARMACEUTICALS LTD

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 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); 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; 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 and estimates is available on request. Past performance is not an indicator of future performance.

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