Communiqué II, 2020 – 19 March 2020

Dear shareholders, friends,

As the year unfolds, we have witnessed the significant downturn of global stock markets which has compounded the decline of CLINUVEL's value. While regretful and painful for many of our shareholders, including staff who own CUV, the reality is that a wider market correction was long predicted. In this Communiqué II, we elaborate on COVID-19 (SARS-CoV-2) to elucidate and clarify some myths, and to provide a rational perspective on the current crisis.

It was with a certain foresight on conceivable market fluctuations that we had consistently built cash reserves while maintaining a conservative fiscal policy. Irrespective of the regulatory, clinical and commercial progress, at CUV we aim to navigate through these downturns with operational leeway, without being affected in our business expansion. Reviewing the internal targets we set every year, we have long pledged to become independent of equity funding and put counter-cyclical shock absorbers in place to withstand the downswings of global economies.

While US market volatility is based on realised volatility and implied option prices of the S&P 500, the recent surge of the VIX-index above 75 is indicative of shockwaves felt across the globe. The 52-week lows and highs of a midcap often follow a more pronounced trajectory, and as uncertainty and volatility reigns in the markets we need to be calm and determined. I believe a publicly listed pharmaceutical entity needs, as much as it can, to focus on its R&D business and develop a longer-term immunity to adverse economic disruptions. Over the past decades I have lived through the aftermath of market corrections reverberating longer than the most lauded economists tended to predict; the crash of October 1987 caused a long-term effect, as did the significant correction in September 2008.

The best one can do in these exceptional circumstances is to concentrate on developing more technologies and indications for value to be recognised when economic conditions normalise; CLINUVEL is poised to develop more commercial technologies in several unmet diseases and – when successful – it will most likely see higher valuations than at its peak in October 2019, since the Company will be rerated with multiple technologies. In the meantime, we serve EU and US patients and their families, and remain concentrated on our mission.

SCENESSE® FOR VITILIGO – NORTH AMERICAN PATIENT POPULATION

As reported on 3 March our teams will meet with the US Food and Drug Administration (FDA) for a designated Type C meeting to discuss the final development program for SCENESSE® (afamelanotide 16mg) in generalised vitiligo.[1] I refer to our Vitiligo Communiqués I-III (2018-2019) reviewing the principal pharmacology of the drug in this disorder. At time of publication the lock-down by the US and European countries is most likely to last for several weeks, at a minimum. There is currently no reason why the FDA meeting would not go ahead, unless US federal agencies cease operations in the next weeks.

Of particular interest is the shift in thinking within the medical community, with vitiligo now recognised as an assembly of subsets of depigmentation disorders with a generalised or segmental character. Several factors play a role in the pathology, genesis and migration in vitiligo, whereby variable rates of depigmentation are presented.

Our teams will be discussing the proposed tools and clinical endpoints with the FDA to arrive at a satisfactory outcome. For instance, the Vitiligo Area Scoring Index (VASI) is a tool commonly used to evaluate the degree of depigmentation per anatomical body site, but it was not designed for monitoring the rate of repigmentation resulting from a treatment.

From another perspective, the lapse of time has provided us with the ability to monitor the emergence of new potential technologies in vitiligo and assess the competitive position SCENESSE® would obtain, its future clinical use and main advantages. Here, we are quite clear on how the drug would be of clinical use in years to come. Moreover, the FDA will have had the time to review other vitiligo protocols and will be more experienced in reviewing the disorder than had been the case for erythropoietic protoporphyria (EPP).

Our team worked in a structured manner and took on board the advice obtained from the FDA during the past years to meet a number of challenges progressing afamelanotide in the depigmentation disorder [see figure to the right].

In our clinical decisions – which apply to all our chosen indications – we forge a dialogue with global experts in a particular medical field early in the process. In vitiligo there is a group of clinicians and academic experts who provide periodic feedback on

(i) clinical utility of SCENESSE®;
(ii) emerging and existing technologies;
(iii) magnitude of the clinical problem; and
(iv) optimum therapeutic response.

The next FDA meeting is the penultimate occasion before the Company anticipates filing its dossier for marketing authorization for vitiligo in the US. Therefore, much preparation has gone into this meeting to explain the intended label for SCENESSE® as a therapy for vitiligo patients. The results of the upcoming trials will need, of course, to justify the data package to be submitted.

The position of the drug within the limited armamentarium of treatments in vitiligo is an important variable when deciding how to propose the label of SCENESSE®. This will be a subject of discussion on 29 April.

All parts will come together for us to prepare the commercial position of SCENESSE® in vitiligo once certainty is obtained on clinical progress, the size of the trials and the key prescribers in North America.

The most essential part of this program remains safety, since CLINUVEL will be first to combine its hormonal treatment with a known carcinogen (narrowband ultraviolet B or NB-UVB, phototherapy). The regulatory authorities will be expected to scrutinise the combination therapy, and in anticipation of this we have completed another pre-clinical study simulating human use of the therapies. Contrary to perceptive belief, it is understood that afamelanotide provides a dermal protective effect while reducing the quantum of UVB irradiation to the skin. The one aspect which has built our credibility with regulators over the years is our emphasis on and attention to clinical safety; the Company's being is based on protecting our patients from possible adverse events (side effects). The very focus on safety is the foundation for our long-term success, and the rigour provided by our global pharmacovigilance team is applied to vitiligo.

SCENESSE® - US DISTRIBUTION

The characterisation of the EPP treatment has required much thought, given most commercial health insurers and government health insurers (i.e. Medicare, Medicaid, etc.) were unfamiliar with the genetic metabolic disease, its symptomatology, manifestation and possible treatment.

Systematically, our teams are working to make SCENESSE® available in the US. For background understanding, we briefly revise the system comprising three billing codes now assigned to SCENESSE®, which required our intervention over the past months. While some insurers have attempted to assign a common billing code for the drug, our market access team had to advise these insurers of the correct future billing code. It is imperative to secure the most accurate code for the treatment and administration procedure with SCENESSE® as it would have consequences down the line on the reimbursement of the clinical procedure to healthcare providers, and the total cost of the treatment patients will receive across all 50 states.

Essential is the realisation that SCENESSE® will only be available through specialised trained and accredited centres; and not through individual pharmacies or specialty pharmacy chains. The trained and accredited healthcare providers receive the prescribed specialty drug and administer the drug for his or her EPP patients at the outpatient hospital facility. Hence, the US health insurers bill SCENESSE® under medical benefit rather than a pharmacy benefit.

The International Statistical Classification of Diseases and Related Health Problems (ICD-10) is a medical classification list by the World Health Organization (WHO). The ICD-10 is applicable to the treatment provided with SCENESSE® for the specific metabolic disease – erythropoietic protoporphyria (EPP) – and deemed a medical necessity. This code is also essential in the billing process for US insurers.

The second code concerns the Current Procedural Terminology (CPT), which is updated annually by the American Medical Association. We obtained the adequate 5-digit code for the afamelanotide subcutaneous administration, given the implantation takes place with a bio-resorbable compound as opposed to more conventional non-degradable materials. In introducing afamelanotide, we learned how the innovative treatment needed to find a place in an established coding system which had not yet accommodated for bio-resorbable hormonal therapy for a metabolic disorder.

The Healthcare Common Procedure Coding System (HCPCS) allows for the drug coding to be used by healthcare providers for uniform diagnoses, services and care to be characterised. J-codes are part of the billing system used by healthcare providers in order to fulfil billing requirements, and these codes are applicable to injectable prescriptive drugs which are not self-administered. For SCENESSE®, the first J-code has been allocated and it is most likely that other J-codes will be applicable.

Last we obtained the National Drug Code (NDC), a unique 10-digit product identifier for human drugs in the United States. The three segments of the NDC identify the labeller, the product, and the commercial package size. The labeller code is assigned by the FDA, while the product and package code are assigned by CLINUVEL.

In the coming weeks, the recommended allocated product and treatment codes will be made public as well as the billing methodology for SCENESSE® for various patient categories selected to receive treatment; a distinction will be made between government insured patients (i.e. Medicare, Medicaid, etc.) and commercially insured patients.

Our team has been asked to meet the riveting challenge of providing access for American EPP patients seeking afamelanotide treatment. In an impenetrable US system, which provides a role for government, employers and employees, those who are on social welfare and below the Federal Poverty Level (FPL), the aim has been to cater for all patients who eventually seek SCENESSE® treatment. As a reference, the FPL for a household of three in the US is US$21,720. We are establishing a system providing for the various patient groups.

As a starting point, US patients face the challenge of paying for a minimum “deductible”, an amount paid out of pocket by the patients before the health insurers will pay any expenses. Understanding the range between deductibles and out-of-pocket maximum per health insurance plan as well as the insurance status per patient provides a model for determining which category requires further assistance.

As most of the US readers will know – but less familiar to audiences from other continents –there is an "out-of-pocket maximum", a limit that patients are asked to pay for medical services per annum. In exceeding this amount, depending on co-payments, and co-insurance for in-network care and services, the health plan (insurance cover) may pay 100% of the costs of the covered medical benefits.

To put all information into perspective, the out-of-pocket maximum for US patients in 2019 was $7,900 and for 2020 $8,150 for individual coverage, with the amount doubled for family coverage.

SCENESSE® is earmarked as a specialty drug and categorised as a Tier 4 prescriptive therapy administered in a medical setting (i.e. doctor's office or outpatient hospital facility). Various healthcare plans will require co-payment from the insured EPP patients. Our teams have been working towards solutions to ensure equitable treatment of US EPP patients.

The next step is the implementation of a staged roll out of SCENESSE® in the US. In keeping with our preparations, and through analysis of peers which have most recently launched orphan therapies, the planned distribution follows a best pattern to eventually maximise the uniform treatment across all US states. Needless to state that we are all counting down the clock to see the first US patient treated with SCENESSE®, while the FDA is reviewing the post-authorisation protocol for medical data entry in the Global EPP Disease Registry (GEDR). A recent question – whether CLINUVEL would have the resources to follow up EPP patients for eight years – needs to be answered affirmatively and without further doubt, since the long-term monitoring is part of our core business. As news around the virulence of COVID-19 emerges from the US, we will provide updates on how this may impact CLINUVEL.

BUSINESS EXPANSION

The Group recently announced further expansion of our VALLAURIX (Singapore) operations, and work is now underway to see our new operations built and accredited within the second half of 2020. The laboratories will have different functions, but the overall objective is to bring all analytical services inhouse. Analytical chemistry is an ineffaceable part of the development of both new therapies and a paediatric formulation. The development of assays, methodologies and programs to evaluate the pharmacology and biological behaviour of our drugs will save the Company significant costs in the future. The new laboratories will be operational on 1 July, while we continue working out of the current lab.

Headcount within our global operations is increasing as we add both new senior managers and assisting managers to our team, much in line with the plan shared by Chair Willem Blijdorp in his recent letter. We have taken a long-term view towards the development of our professionals and it is an engaging challenge for the management team to ensure this continues according to plan.

As to our approach to inorganic expansion, we continuously review growth opportunities. Some of these are identified by us, others by investment banks scouting the world for compatible technologies and teams. In general, we have been looking at innovative technologies coming with experienced managers.

The question we have received is whether an acquisition would be a distraction to the CUV business. There are pros and cons to expanding the business by acquisition and depending on the target, one arrives at a balanced view. The ability to integrate and make the business profitable are just two of our main criteria. Our current state of mind focuses on our key objective, to complete the distribution of SCENESSE® to US EPP patients, the rest of our activities will follow in due course.

At the Annual General Meeting of Shareholders in November 2019 we disclosed the final part of the photoprotective development of afamelanotide: evidence on its ability to repair UV-induced DNA damage. In the coming weeks we hope to reach agreements with hospitals and authorities to conduct our first trial in DNA repair. It is an important development, one which started clinically in 2006 and we now want to complete. Yet it required a measured scientific approach and depended on the FDA's positive evaluation of the drug in EPP. As the clinical trial starts, we will share the objectives and pathways leading to generating data on the role of melanocortins on genomic deficiencies. The relevance of providing evidence of the

effects of melanocortins on UV-provoked skin damage (see Scientific Communiqués III and IV on our website) is of much value both scientifically and clinically.

COVID-19

On 12 March the Director General of the WHO, Dr Tedros Ghebreyesus, declared a pandemic arising from the COVID-19 virus. We deem it appropriate to present you a factual update as a way of informing our stakeholders of the current phenomenon to ensure all take calm and calculated decisions.

This Corona virus is believed to have followed on from the respiratory syndrome coronavirus (MERS-CoV) and SARS. The International Committee on Taxonomy of Viruses termed this particular virus COVID-19. There is wide speculation that the virus originates from animals, possibly bats.

The Corona viruses consist of four families:

a. alphacoronavirus (alphaCoV);
b. betacoronavirus (betaCoV);
c. deltacoronavirus (deltaCoV); and
d. gammacoronavirus (gammaCoV).

Our interest goes to the beta-lineage of Corona viruses. Viruses contain an envelope, and this particular virus has spike-like glycoproteins (S1/S2) giving it a crown-like shape when viewed under the microscope, hence "Corona". The envelope consists of positive-stranded RNA viruses with nucleocapsid, and enables the virus to attach to the receptor-binding motif (RBM) that directly contacts ACE-2 (angiotension-converting enzyme 2), which are expressed as early as in the tissue of the oral mucosa, airway epithelia and lung parenchyma. There is strong suggestion that COVID-19 exhibits the same characteristics as that of SARS-CoV (2002-2003) using ACE2 as its target receptor.

Comparing the genome of COVID-19 with that of SARS-CoV showed 82% identical nucleotides, hence the naming of this virus SARS-CoV-2. The virus itself needs various proteins to invade human cells in order for the genome of the virus to enter the host cells and start the infection (RNA mediated). Current research is aimed at targeting these proteins to prevent the virus entry in the human host in the first place.

Although the virulence is relatively low, the absolute numbers in Italy are sufficient for the Italian government to call for a nationwide lock-down: COVID-19 confirmed in 31,506 residents and causing 2,503 deaths (7.945%).[2] Other European countries have since adopted this "lock-down" approach.

John Hopkins University[2] keeps track of the daily new COVID-19 cases reported in each country, on 18 March the status was as follows:

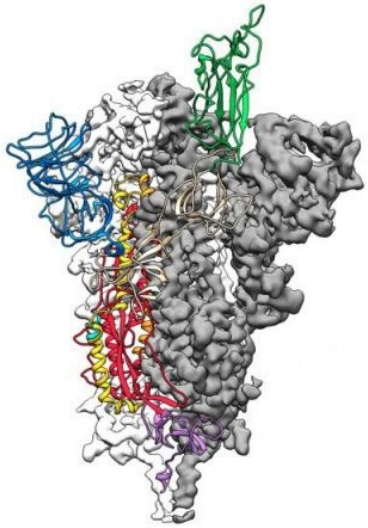
Australia	565
Austria	1,471
Belgium	1,243
France	7,792
Germany	9,367
Iran	16,169
Italy	31,506
Japan	882
Netherlands	1,708
Norway	1,471
South Korea	8,413
Spain	11,826
Sweden	1,196
Switzerland	2,742
UK	1,960
USA	6,524

According to the recent publications (18 March) there were 8,226 deaths reported from COVID-19 and 203,614 patients had contracted the virus, far exceeding the SARS outbreak which killed 774 individuals worldwide. In total 82,091 (40.3%) patients have recovered from Corona. By the time of publication these numbers are certain to have evolved.

It is important to realise that approximately half (49.0%) of the critical patients who have died were affected by pre-existing diseases or conditions such as cardiovascular disease, diabetes, chronic respiratory disease, and oncological diseases. Clearly, as with other infectious disease, one's immune status is important. Those diseased patients in Wuhan (CN) who presented severe clinical manifestations showed the most frequently severe pneumonia, acute respiratory distress syndrome, sepsis (rapidly spreading systemic

infection), and septic shock. In half of the patients the disease has been mild in nature. Literature reports illustrate that the Corona viruses can be inactivated by disinfectants such chloroform, lipid solvents including ether (75%), ethanol, chlorine-containing disinfectant and peroxyacetic acid. The WHO recommends that isolation is the best way to combat the virus (see breakout box below), while EU governments call for social distancing and group immunity to be achieved over time.

CLINUVEL has implemented measures across its teams to keep its members safe, informed, and productive during this time and to minimise the impact of the outbreak on the business.



Right: 3D atomic scale map or molecular structure of the SARS-2-CoV protein "spike" which the virus uses to invade human cells. [Image: © Jason McLellan/Univ. of Texas at Austin].

The WHO has issued the following general recommendations related to COVID-19:

1. Avoid close contact with patients suffering from acute respiratory infections.
2. Wash your hands frequently, especially after contact with infected people or their environment.
3. Avoid unprotected contact with farm or wild animals.
4. People with symptoms of acute airway infection should keep their distance, cover coughs or sneezes with disposable tissues or clothes and wash their hands.
5. Strengthen, in particular, in emergency medicine departments, the application of strict hygiene measures for the prevention and control of infections.
6. Individuals that are immunocompromised should avoid public gatherings.

The most important strategy for all of us is to frequently wash our hands and use portable hand sanitiser and avoid contact with our face and mouth after interacting with a possibly contaminated environment.

PUBLIC AND INVESTOR RELATIONS

As our IR program is being executed, the COVID-19 epidemic has caused a number of conferences and speaking slots to be cancelled. The American Academy of Dermatology in Denver and its satellite meetings have been called off due to the international travel of many delegates. We will update our readers as the quarter evolves, with a summary of current events given in the table on the right. (Continued on next page)

Month	Planned event
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
April	Goldman Sachs Healthcare Conference, Sydney (TBC)
May	UBS Healthcare Conference, NYC UV & Skin Cancer Prevention Conference, Mechelen, Belgium Congress Italian Society of Dermatology and Venereology, Florence
June	Jefferies Healthcare Conference, NYC American Society for Photobiology Meeting, Chicago Int'l Congress on Porphyrins and Phthalocyanines, Buffalo, NY
July	British Assoc. of Dermatologists, Manchester
September	ESPD Photodermatology Day (TBC)
November	Jefferies Healthcare Conference, London (TBC)

SUMMARY

In the wake of the COVID-19 outbreak, we understand the anxiety of our patients and also some of our shareholders. As with other outbreaks of disease in the past decade, remaining calm and assuming a rational mind provides time to reflect. We are in unprecedented territory. The day this state of emergency has ceased we will need to resume a life heeding to present warning and anticipating the possibility of future pandemics, but also reminding ourselves of our state of mind in March 2020. Many families are affected in the world, and our state of being is a blessing in light of all the mischief taking place.

The effect of the health hazard on CLINUVEL's business is hard to predict, and we will monitor the clinical attendance of EPP patients in the European Union. If material changes to our business are observed, we will share the news as it emerges.

The outlook of the Company and team for the year remains positive. Our vision for our Company to prosper and develop translational research to markets is unchanged. Fundamental work at CLINUVEL continues throughout times of global hardship and we are working diligently towards the objectives outlined in 2019.

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.

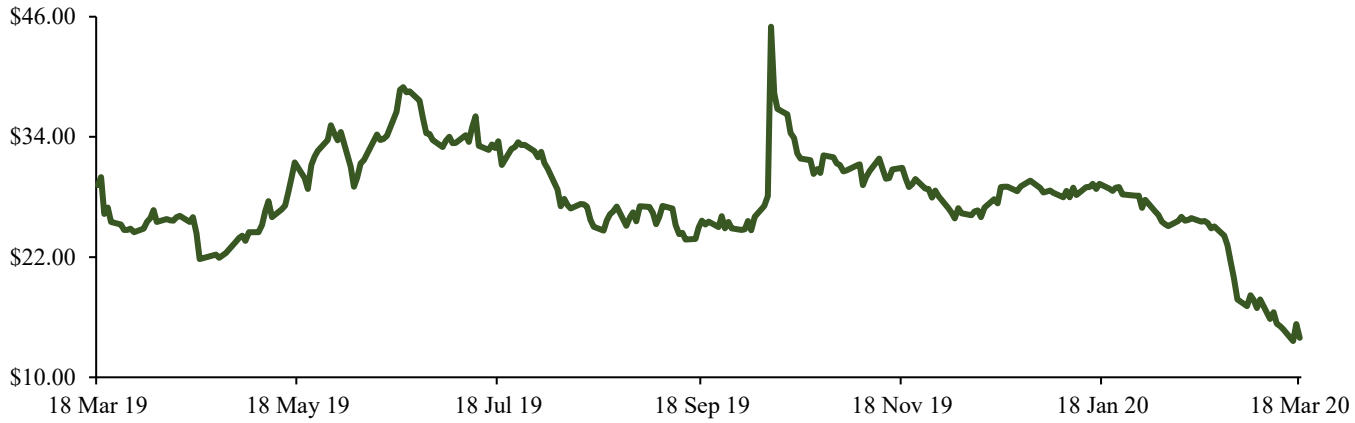
[2] Numbers correct as at 1200GMT on 18 March 2020, Source: FT.com, John Hopkins University (https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6).

ASX: CUV

Shares on issue	49,410,338
Fully diluted	49,563,046
Market cap (18 March 2020)	A$690m

Share price

(ASX: CUV 18 Mar 2019 – 18 Mar 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, 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 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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