Press Release

THE LANCET publishes promising data of APEIRON's APN01 (rhsACE2) to treat COVID-19 in named patient use

- **Case study from promising first COVID-19 patient treatment with APN01 supports APEIRON's ongoing pivotal Phase II clinical trial**

- **First data on the effect of blocking the spike protein in COVID-19 patient confirm mode of action of APN01 specifically targeting SARS-CoV-2**

Vienna, Austria, 25 September 2020: APEIRON Biologics AG today announced that first, encouraging data with its clinical drug candidate APN01 (rhsACE2) to treat severe COVID-19 were published in the peer-reviewed journal *The Lancet Respiratory Medicine* [1].

The Case Report describes the first treatment of a patient suffering from severe COVID-19 with APN01 in named patient use. The data published show the expected observations of an adaptive immune response, a rapid loss of virus load and reduction in inflammatory mediators, and the development of high titers of neutralizing antibodies against SARS-CoV-2 leading to a significant clinical improvement of the patient treated.

Dr. Alexander Zoufaly, MD, Senior physician at the Department of Infectious Diseases/Clinic Favoriten and author of the publication comments**: "**ACE2 is at the center of COVID-19 research and drug development. In this instance, we have now provided first data on soluble ACE2 therapy in a patient with SARS-CoV-2 infection. The results from this named patient use are encouraging and support the rationale to further explore APN01 as a therapy to treat COVID-19 in clinical trials."

"Providing first data on the effect of blocking the viral Spike glycoprotein in patients with COVID-19 is of paramount importance. The data confirm the mode of action of APN01 specifically targeting the SARS-CoV-2 virus," says **Prof. Josef Penninger, MD, co-inventor of APN01, founder of APEIRON Biologics AG, member of its supervisory board, Professor at the University of British Columbia and co-author of the publication.** "Our findings from the first SARS epidemic and recent research have identified ACE2 as the entry door for both corona viruses, SARS-CoV and SARS-CoV-2, to infect human cells. The new data further support the ability of APN01 to locking the door for the virus. Importantly, in contrast to basically all other drug candidates, APN01 has a dual action – it blocks the virus and can protect the lung, blood vessels or the heart from injury via its enzyme function. The compassionate use findings provide essential data that this important enzyme function of APN01 is preserved in treated COVID-19 patients."

Peter Llewellyn-Davies, CEO of APEIRON Biologics AG, adds: "We are delighted our drug candidate APN01 may have helped this patient to overcome the life-threatening disease and are confident to confirm these positive results in our ongoing and progressing pivotal clinical

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[1] Zoufaly A. et al., *The Lancet Respiratory Medicine*, 2020, S2213-2600(20)30418-5 DOI: https://doi.org/10.1016/S2213-2600(20)30418-5

Phase II trial. The further scientific validation by this renowned journal encourages us in our efforts to providing an efficacious therapy against COVID-19 for the benefit of patients and society."

Key findings of the publication: APN01 (soluble ACE2) infusion showed the expected enzymatic activity and modulation of the renin angiotensin system. The APN01 infusion correlated with a gradual reduction in levels of multiple disease relevant inflammatory mediators over the studied time period. The infusion of APN01 also correlated with a rapid loss of detectable viremia and slightly delayed reduction in viral titers in tracheal samples and nasopharyngeal swaps. APN01 infusion was fully compatible with an adaptive immune response and the development of high titers of neutralizing antibodies against SARS-CoV-2.

About APN01 / alunacedase alfa (soluble ACE2)

APN01 / alunacedase alfa (rhsACE2) is a well-advanced drug candidate for the treatment of COVID-19 and one of the few therapeutic approaches specifically directed against the corona virus. According to experts, if the current Phase II study is positive, accelerated market approval could probably take place.

The company-sponsored Phase II trial is ongoing in Austria, Germany, Denmark, UK, and Russia and is expected to be expanded to the US. The double-blind, randomized, placebo-controlled study aims to treat 200 patients with severe COVID-19 disease.

The specific targeting of SARS-CoV-2 by APN01 was recently confirmed by preclinical results published in the peer-reviewed publication *CELL* [2].

About APEIRON Biologics AG

APEIRON Biologics AG is a European private biotechnology company based in Vienna, Austria, that specializes in the discovery, development and commercialization of novel immunotherapies for cancer and respiratory diseases. APEIRON's APN01 / alunacedase alfa (rhsACE2) is undergoing a Phase II trial to treat COVID-19. APEIRON has an approved product on the market, Qarziba®, for the treatment of pediatric neuroblastoma patients, which is distributed by EUSA Pharma. The company's clinical program APN401 is a first-in-class autologous cellular therapy to strengthen immune reactivity via targeting the intracellular master checkpoint, Cbl-b. APEIRON's projects and technologies are based on a strong patent portfolio and partnerships with leading pharmaceutical companies and academic institutions. Further information at www.apeiron-biologics.com

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[2] Monteil V. et. al., *Cell*, 2020, 181(14);905-913.e7 DOI: https://doi.org/10.1016/j.cell.2020.04.004

FORWARD-LOOKING STATEMENTS

This press release contains certain forward-looking statements that involve risks and uncertainties. These statements reflect APEIRON's opinion at the time of this press release. Such forward-looking statements are neither promises nor guarantees, but depend on many risks and uncertainties, many of which are beyond the control of APEIRON's management. This could cause actual results to differ materially from those projected in these forward-looking statements. We expressly assume no obligation to publicly update or revise any forward-looking statements regarding changed expectations of the parties or regarding new events, conditions or circumstances on which these statements are based.