APEIRON's respiratory drug product to start pilot clinical trial to treat coronavirus disease COVID-19 in China.

- Investigator Initiated Trial (IIT) to start in China, with an international team of experts from China, Austria, and Canada.
- 24 patients with severe COVID-19 to be treated in a randomized, dual-arm trial with Apeiron's ACE2 drug product APN01
- APN01 was previously proven to be safe and well tolerated in Phase I and Phase II clinical trials
- With its unique ACE2 approach APN01 offers an alternative treatment option to other approaches currently in development

Vienna, Austria, 26 February 2020: APEIRON Biologics AG, a biotechnology company with an approved product on the market as well as a broad preclinical and clinical pipeline, today announced the launch of a Pilot investigator-initiated clinical trial (IIT) with APN01, a recombinant human angiotensin-converting enzyme 2 (rhACE2), to treat patients with severe coronavirus infection in the People's Republic of China.

The randomized, unblinded trial will treat 24 patients for seven days to obtain preliminary data on the impact of rhACE2 on biological, physiologic, and clinical outcomes, as well as safety in patients with severe SARS-CoV-2 infection. These data will be assessed to ascertain whether a Phase 2B clinical trial in a larger number of patients is warranted.

The trial is being supported by a global team of leading experts: Intensive care specialist, Prof. Arthur Slutsky, Scientist, St. Michael's Hospital, Toronto, and Prof. of Medicine, Surgery and Biomedical Engineering at the University of Toronto (Toronto, Canada) and Prof. Haibo Zhang, Prof. of Anesthesiology, St. Michael's Hospital, University of Toronto; Prof. Nanshan Zhong and Prof. Yimin Li, both of the Guangzhou Institute of Respiratory Health and leading physicians in fight against COVID-19 in China, will oversee the trial; and Prof. Josef Penninger, Scientific Director and Professor of the Life Science Institute of the University of British Columbia, Canada.

"To address this unfortunate crisis and dreadful disease our team has at short notice been able to bring together a worldwide team of experts and scientists. Our drug candidate APN01 has been proven safe and well tolerated in patients in previous clinical PhI and PhII trials. We are delighted and proud that we can now start treating infected patients in China." **said Peter Llewellyn-Davies, Chief Executive Officer of APEIRON Biologics AG**.

"Our lab provided the first *in vivo* proof that ACE2, which we had cloned and made the first mutant mice, is the essential receptor for the SARS-CoV-2 and that ACE2 has the potential to protect the lung from injury by collaborating with Prof. Chengyu Jiang at PUMC in Beijing. I am excited that based on our research and developments, the potential of APN01 (soluble human ACE2 protein) for the treatment of patients suffering from the novel coronavirus infection is now being explored in clinical trials," stated **Prof.**

Penninger, MD, co-inventor of APN01, founder of APEIRON, member of its supervisory board and Professor at the University of British Columbia.

"ACE2 has been shown to be essential for early viral infection of the SARS-CoV virus, which spread rapidly around the world in 2003. The novel coronavirus SARS-CoV-2 also relies on the ACE2 receptor to infect human cell. Thus, treatment with recombinant human ACE2, can be used to block viral spread, and may minimize lung injury, and multiple organ dysfunction, and ultimately decrease mortality in patients with COVID-19." **explained Prof. Slutsky.**

After seven days of treatment, the trial data will be evaluated and potential further clinical development will be assessed by APEIRON and the IIT team.

This trial cooperation has been supported by Dr. Liqun Zhang and team of Angalpharma Co., Ltd (Suzhou, China), for coordinating the Chinese clinical trial with the support of dMed Pharmaceutical Co., a CRO team based in China.

About APN01
APN01 is a recombinant human Angiotensin Converting Enzyme 2 (rhACE2) and was developed by APEIRON for the treatment of acute lung injury (ALI), acute respiratory distress syndrome (ARDS) and pulmonary arterial hypertension (PAH). After licensing from APEIRON in February 2010, GSK conducted trails from 2014 to 2017 to treat ALI and PAH and (ARDS), the latter being the major source of Covid-2019 mortalities, the disease caused by the new corona virus 2019-nCoV. In 2019, APEIRON obtained the APN01 licenses back from GlaxoSmithKline (GSK) for further clinical development, after a strategic refocusing of GSK to oncology.

The ACE2 receptor is expressed in human airway epithelia as well as lung parenchyma and was previously identified as the gateway, which the SARS virus uses to infect the cells. ACE2 is also the critical receptor for the new virus 2019-nCoV to enter human cells. Thus, treatment with recombinant human ACE2 could be used to not only block viraemia but also protect lungs from injury. APEIRON currently has the full licenses, clinical data and protocol from GSK, GMP production technology and stored GMP grade rhACE2 available for immediate use in trials in China. The drug candidate is administered intravenously as an infusion and has shown safety and tolerability in 89 patients and volunteers.

About APEIRON Biologics AG
APEIRON is a privately-held European biotech company based in Vienna, Austria, focused on the discovery and development of novel cancer immunotherapies. APEIRON received EU marketing approval for APN311 (Dinutuximab beta, Qarziba®) in May 2017 for the treatment of pediatric neuroblastoma patients and out-licensed global, exclusive rights for this product to EUSA Pharma Ltd. APEIRON now leverages its proprietary master checkpoint blockade mechanism to enable the human body's natural defense mechanisms to fight the tumor. APEIRON's clinical lead program APN401 is a first-in-class autologous cellular therapy to strengthen immune reactivity via an intracellular master checkpoint, Cbl-b. APEIRON's projects and technologies are bolstered by a strong patent

portfolio. APEIRON's development expertise is validated through partnerships with leading pharmaceutical companies and academic institutions.

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FORWARD LOOKING STATEMENTS

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