Press Release

APEIRON Biologics: Patient recruitment completed in Phase II COVID-19 Clinical Trial of APN01

- Results of the double-blind, placebo-controlled trial expected in Q1 2021
- Preparations for rolling Marketing Authorization Application in Europe commenced
- Trial results to confirm unique triple mode of action to prevent infection, organ injury and inflammation.

Vienna, Austria, 04 December 2020: APEIRON Biologics AG today announced that patient recruitment of its ongoing Phase II clinical trial with APN01 to treat COVID-19 was completed. The results of the international, multicenter, double-blind, randomized and placebo-controlled trial are expected in Q1 2021.

APN01 (alunacedase alfa) is the recombinant form of the human angiotensin-converting enzyme 2 (rhACE2) with a unique triple mode of action: APN01 has the potential to prevent cells from infection with the SARS-CoV-2 virus, reduce injury to multiple organs and additionally to treat the inflammatory reactions in the lungs caused by COVID-19. The specific targeting of SARS-CoV-2 by APN01 was recently confirmed by preclinical results published in the peer reviewed publication *CELL*.

The ongoing Phase II trial compares APN01 to placebo with approximately 100 patients per treatment arm in severely infected COVID-19 patients at multiple sites in Germany, Austria, Denmark, UK and Russia. The primary objective of the trial is to assess the clinical efficacy and safety of APN01 in severe COVID-19 patients using, among other criteria, the need for invasive mechanical ventilation. Secondary objectives include the evaluation of measurable biological biomarker changes following treatment with APN01.

"APN01 is one of the most advanced COVID-19 drug candidates and the only clinical stage treatment specifically targeting SARS-CoV-2. We have seen clear results in preclinical studies and named patient use confirming the mode of action and clinical benefit of APN01 in COVID-19 patients and feel encouraged to confirm efficacy with this clinical phase II trial," said **Peter Llewellyn-Davies, Chief Executive Officer of APEIRON Biologics AG**. "Currently, we are defining with the European Medicines Agency (EMA) a potential rolling Marketing Authorization Application (MAA) submission to make this drug candidate available for severely suffering patients as fast as possible, subject to positive clinical results."

About APN01 / alunacedase alfa (soluble ACE2)

APN01 is a recombinant human Angiotensin Converting Enzyme 2 (rhACE2). Before clinical development in COVID-19 started in April 2020, APN01 successfully completed several clinical trials in severe respiratory diseases like acute lung injury (ALI), acute respiratory distress syndrome (ARDS) and pulmonary arterial hypertension (PAH). Lung injuries caused by ARDS are one of the major sources of severe COVID-19.

In these clinical trials, safety and tolerability of APN01 were demonstrated. A peer reviewed publication *The Lancet Respiratory Medicine* recently published encouraging safety and efficacy data for APN01 for the treatment of COVID-19 in a Case Study with named patient use.

Unique triple Mode of Action

- *Prevent infection / virus neutralization:* APN01 is the soluble form of ACE2, the receptor for entry of SARS-CoV2 into the cell. Binding of APN01 to viral spike protein prevents binding of the virus to cell surface receptors and thereby prevents infection of cells.
- *Prevent organ injury / reduction of disease mediated organ pathology:* APN01 shifts the Renin-Angiotensin-System (RAS) towards repair and reduction of injuries to blood vessels and organs including the lungs, kidneys or the heart.
- *Control inflammation*: APN01 reduces the release of pro-inflammatory cytokines and chemokines which play an important role in lung injury and cytokine storm, thereby reducing the uncontrolled inflammation triggered by SARS-COV-2.

About APEIRON Biologics AG

APEIRON Biologics is a privately held European biotech company based in Vienna, Austria, focused on the discovery and development of treatments for respiratory diseases and novel cancer immunotherapies.

APN01 (rhsACE2, alunacedase alfa), a soluble recombinant version of the SARS-CoV-2 cell entry receptor ACE2, has a unique triple mode of action to treat COVID-19 and is undergoing a double blind, placebo-controlled Phase II trial in Europe and Russia.

APEIRON received EU marketing approval for APN311 (Dinutuximab beta, Qarziba®) in 2017 for the treatment of pediatric neuroblastoma patients and out-licensed global, exclusive rights for this product to EUSA Pharma Ltd.

APN401´s proprietary process brings in a paradigm change in cancer treatment to fight hematological and solid tumors. The clinical program is a first-in-class ambulatory autologous cellular therapy to strengthen immune reactivity via an intracellular master checkpoint inhibitor, Cbl-b.

APEIRON Biologics´ 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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FORWARD LOOKING STATEMENTS

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