



COVID-19: targeted treatment trial launched in Vienna

(Vienna/Heidelberg/Cologne/London, 22 December 2020) A phase II clinical trial of a treatment for COVID-19 patients is currently starting at the Medical University of Vienna as a sub-study of the Austrian CoronaVirus Adaptive Clinical Trial (ACOVACT). The trial was initiated as an academia-industry collaboration (investigator Initiated trial) between Apogenix AG, a biotech company based in Heidelberg, and their scientific consultant Henning Walczak and his teams at the University of Cologne and University College London (UCL).

Patients with severe to critical COVID-19 are now being treated with an immunotherapeutic drug, the Fas ligand blocker asunercept, from Apogenix within the framework of the Austrian CoronaVirus Adaptive Clinical Trial (ACOVACT). ACOVACT is a randomised, controlled, multi-centre, open-label clinical trial sponsored by MedUni Vienna. Within ACOVACT, different treatments for COVID-19 are compared to one another.

The sub-study of ACOVACT was initiated by Henning Walczak, Michael Bergmann and Apogenix. Walczak is an expert in the role of cell death and inflammation in inflammatory disease and cancer. He is Alexander von Humboldt Professor of Biochemistry at the Cluster of Excellence for Ageing Research (CECAD) at the University of Cologne and Professor of Cancer Biology at the UCL Cancer Institute. Bergmann is a surgeon at MedUni Vienna and an expert on oncolytic viruses and cancer immunotherapies. Apogenix develops innovative immunotherapeutic agents for the treatment of cancer and viral diseases such as Covid-19.

Novel approach in the treatment of COVID-19

The study is based on a scientific concept developed by Walczak and Bergmann together with Apogenix. In conjunction with results published by other researchers, they hypothesised that tissue damage and lung failure in patients with severe COVID-19 may in fact be the result of the overactivity of so-called death ligands rather than the viral infection itself.

Death ligands are proteins normally produced by our own body in the course of immune defence. The immunotherapeutic that is now being trialled intercepts the death ligand known as Fas ligand or CD95 ligand.

"It appears that SARS-CoV-2 infection induces an overreaction of our immune system, resulting in overproduction of Fas ligand. This killer protein can then kill healthy, uninfected cells in the lungs of COVID-19 patients, thus causing lung damage," explains Walczak. "The concept of blocking cell death in the treatment of COVID-19 is a completely novel one. We



are excited to see the outcome of this clinical trial," adds Bergmann. Hitherto, the search for effective treatments for COVID-19 has mainly focused on drugs that aim to interfere either with the virus itself or with the effects of the cytokine storm. "However, by the time doctors get to see patients, the viral load has normally already dropped substantially and the systemic cytokine storm was shown to be quite low in COVID-19 patients when compared to diseases such as septic shock, for example," says Bergmann.

"Blocking the Fas ligand offers the opportunity to interfere with the cause of severe COVID-19. By blocking cell death, we are preventing the fuel from feeding the fire rather than trying to put out a fire that is constantly fed," says Christian Schörghofer, who is coordinating the trial together with Bernd Jilma (both from MedUni Vienna's Department of Clinical Pharmacology).

Thomas Höger, Chief Executive Officer of Apogenix, comments: "It has been an exciting endeavour to team up with Henning Walczak, a co-founder of our company, and the team from MedUni Vienna in a joint effort to ascertain whether this novel treatment is effective. We hope that our new therapeutic can help improve the treatment of severe COVID-19 and also see the therapeutic potential of such a treatment for other viral diseases such as Influenza."

This phase II clinical trial complements another stand-alone phase II clinical trial by Apogenix with the same therapeutic in patients with severe COVID-19 being conducted in Spain and Russia.

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About Medical University of Vienna

Medical University of Vienna (MedUni Vienna) is one of the most traditional medical education and research facilities in Europe. With almost 8,000 students, it is currently the largest medical training centre in the German-speaking countries. With 5,500 employees, 26 departments and two clinical institutes, 12 medical theory centres and numerous highly specialised laboratories, it is also one of Europe's leading research establishments in the biomedical sector.

About Apogenix

Apogenix is a private company developing innovative immunotherapeutics for the treatment of cancer and viral infections, such as COVID-19. The company's pipeline of immunotherapy drug candidates targets different tumor necrosis factor (TNF) superfamily-dependent signaling pathways in order to restore the anti-tumor immune response in cancer patients and reduce lymphopenia and inflammatory cell death in patients with viral infections. Checkpoint inhibitor asunercept, the company's lead immunotherapy candidate, is in late-stage clinical development with PRIME (PRiority MEDicines) designation by the European Medicines Agency for the treatment of glioblastoma.

About University of Cologne

The University of Cologne, founded in 1388, is one of the oldest and - with over 51,000 students - largest universities in Europe. It enjoys an excellent international reputation due to its outstanding scientific achievements and the high quality and diversity of its courses. The Faculty of Medicine closely interlinks teaching, patient care, and research. The CECAD - the Cluster of Excellence on Cellular Stress Responses in Aging-Associated Diseases - of the University of Cologne is one of Germany's first excellence clusters. CECAD, as interdisciplinary research association, focuses on unveiling the molecular mechanisms of ageing and age-associated diseases.

About University College London (UCL)

UCL is a diverse community with the freedom to challenge and think differently.

Our community of more than 41,500 students from 150 countries and over 12,500 staff pursues academic excellence, breaks boundaries and makes a positive impact on real world problems.

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We have a progressive and integrated approach to our teaching and research - championing innovation, creativity and cross-disciplinary working. We teach our students how to think, not what to think, and see them as partners, collaborators and contributors.

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We were the first in England to welcome women to university education and that courageous attitude and disruptive spirit is still alive today. We are UCL.