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COVID-19: Treatment for the most severely affected patients - after promising results in "named patient use" - clinical trial with FX06 starts in France.

F4 Pharma, a clinical-stage biopharmaceutical company developing FX06, an anti-inflammatory therapeutic that has shown to improve vascular integrity, announces today the inclusion of the first patient with severe COVID-19 in a study named "FX-COVID". The randomized, double-blind, placebo-controlled FX-COVID trial which is conducted by AP-HP (Assistance Publique –Hopitaux de Paris) in France, is set up to confirm the efficacy and safety of FX06 in hospitalized patients receiving mechanical ventilation. The goal is to show that FX06 infusion - on top of optimal medical treatment - is reducing the extracellular lung water index and is leading to improved respiratory parameters. By reducing pulmonary vascular hyperpermeability, FX06 is supposed to lead to improved lung function and reduced time of mechanical ventilation. The study will include four intensive care units and is sponsored by AP-HP, the University hospital trust operating in Paris and its surroundings, being the largest hospital system in Europe.

FX06, a substance discovered and developed in the Medical University of Vienna, has a dual mode of action: it is reducing the capillary leak and has anti-inflammatory efficacy. Six severely affected patients treated under named patient use exhibited improved lung function and reduced inflammatory markers. These promising results shall now be confirmed in clinical trials.

Dr. Nicolas Bréchot, Principal investigator of the FX-COVID study commented: "There is a high medical need for treatment options for the most severe cases of COVID-19 and hopefully we will be able to show a benefit for these patients in this controlled study."

Mag. Thomas Steiner, CEO and co-founder of F4 Pharma commented: "All the evidence concerning the excellent safety profile of FX06, its mode of action, its vasoprotective effect are convincing. We believe that FX06 has the potential to be an effective and important therapy for severely affected COVID-19 patients. We will apply for emergency use and conditional marketing authorization as soon as the data from the clinical trials are available."

Dr. Petra Wülfroth, CSO and co-founder of F4 Pharma commented: "FX06 has an innovative mode of action targeting the host response without affecting the innate immune system. There is emerging evidence that the virus – in addition to affecting the lung - causes damage also in other organs. This is due to a general inflammation of the endothelium, the inner layer of the small blood vessels. Our drug FX06 is working on several levels: FX06 is able to improve lung function and to ameliorate the generalized inflammatory process, thus reducing the often fatal consequences of the disease."

Anne Burger, CEO of SIRS GmbH, partner of F4-Pharma in the work on FX06 commented: "Although vaccines are occurring as a silver lining at the horizon, SARS-CoV-2 will be a part of our life for the time to come. There will be still a high medical need for an effective medication for the severe cases of COVID-19. FX06 has shown first promising results in named patient use and we are confident to confirm these results in clinical trials. And – beyond COVID-19 – there is a high potential for FX06 for further indications with a high medical need."

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