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PRESS RELEASE

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CORAT Therapeutics GmbH obtained regulatory authorization for clinical phase Ib/II trial with the SARS-CoV-2 neutralizing human antibody COR-101

- CORAT Therapeutics antibody therapy obtained approval to start its clinical trial.
- COR-101 is a human antibody that blocks virus infection by binding to the spike protein of SARS-CoV-2; it is proven that COR-101 decreased virus load in the lung by more than 99 % in an animal model within three days.
- In contrast to existing medications – the safety design of COR-101 is optimized for the treatment of hospitalized COVID-19 patients with moderate to severe disease.

Braunschweig, March 16, 2021

CORAT Therapeutics GmbH obtained the regulatory approval as well as the favorable opinion from the central ethics committee to conduct the clinical phase Ib/II trial with its antibody COR-101 against COVID-19. COR-101 is a neutralizing human antibody that binds to the receptor binding domain (RBD) of the spike protein of SARS-CoV-2 and is endowed with a unique structural design. It aims to improve the treatment situation of hospitalized COVID-19 patients with moderate to severe disease, a patient group which currently cannot be treated appropriately due to the lack of effective medication. The innovative safety design of COR-101 prevents any Fc-gamma receptor binding and avoids the risk of antibody dependent enhancement (ADE) of disease. The antibody was isolated from convalescent patients and was developed with an accelerated development strategy under guidance of the German regulatory authorities. Experimental studies have shown that COR-101 binds to many mutated variants of SARS-CoV-2, such as the "British" variant (N501Y/E484K, B.1.1.7.), but also to the new and rapidly spreading "Czech" (N439K) or "New York" and "Nigeria" variants (E484K).

"We are very happy to have reached this crucial step in COR-101 development. Many thanks to the support of the State of Lower Saxony and our private investors", comments Dr. Andreas Herrmann, CEO of CORAT Therapeutics, and continues: "We feel confident that COR-101 can fill the gap in the medical need for the treatment of hospitalized COVID-19 patients that have moderate and severe symptoms, where no other specific treatment is available at this time worldwide. The development of specific therapeutics to treat



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COVID-19 diseases is next to vaccination and testing an important pillar to effectively fight the pandemic."

The study (ClinicalTrials.gov ID: NCT04674566) is a randomized, double-blind, placebo-controlled, parallel-group, first-in-human, phase Ib/II study to assess the safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity, and efficacy of COR-101 in hospitalized patients with moderate to severe COVID-19. The study will start in six study centers in Germany and expanded up to 15 study centers in Europe to give fast access to the patients. The overall medical responsibility for the study lies with Prof. Dr. Helmut Salih at the University Hospital in Tuebingen.

COR-101 was developed in close cooperation with the University of Technology in Braunschweig (TUBS) and the human antibody development company YUMAB GmbH. Dr. Thomas Schirrmann, COO of CORAT Therapeutics, who led the preclinical development, commented: "We are convinced that neutralizing antibodies like COR-101 add an urgently needed treatment option for all the patients, who cannot be vaccinated due to other conditions, or all those who do not develop a sufficient immune response after vaccinations. Antibodies are known as very robust, safe, and easy-to-manufacture medications against infections for more than hundred years, and they can close the treatment gap that the current vaccines cannot fill. We are confidently looking forward to obtain a drug that will help patients to recover from COVID-19 and that saves lives."

Further information:

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