PRESS RELEASE

Phase Ii Research Against Covid-19 Launched In France
With Debiopharm's Antiviral Alisporivir

- *Pre-clinical in vitro research from the Mondor Institute of Biomedical Research (INSERM U955) has shown evidence for the effectiveness of alisporivir against the replication of SARS-COV-2 (COVID-19).*[1]
- *A randomized, investigator-initiated, phase II study, conducted by the AP-HP (Greater Paris University Hospitals), has been launched to assess the efficacy and safety of the compound in 90 hospitalized COVID-19 patients from multiple centers in France*
- *Debiopharm has opted to forgo any financial benefit from treatment and pledges to donate all proceeds to a non-profit foundation dedicated to infectious disease research*

Lausanne, Switzerland– January 18th 2021 – Debiopharm (www.debiopharm.com), a Swiss biopharmaceutical company, announced today the first patient dosed in an investigator-initiated, randomized phase II, open-label clinical trial for its antiviral alisporivir (Debio 025). The study will be conducted by the AP-HP to assess the efficacy and safety of the cyclophilin inhibitor in the treatment of early stage, hospitalized COVID-19 patients who do not require medical ventilation andhave not exhibited signs of acute respiratory distress syndrome. The primary objective of this "proof-of-concept" trial is to evaluate the reduction in COVID-19 viral load in alisporivir treated patients. The secondary objective involves the analysis of clinical & radiological efficacy, safety and tolerability of the compound plus Standard of Care (SOC) compared to SOC alone. Patients in the investigational arm will receive alisporivir either orally or *via* a nasogastric tube, at the dose of 600mg twice daily for 14 days during the trial led by Prof. Jean-Michel Pawlotsky, virologist, Head of the Biology and Pathology Department of the Henri Mondor Hospital Group, Greater Paris University Hospitals. The trial, supported by both the hospital group and Debiopharm, will be carried out in multiple centers in France including the Henri Mondor Hospital Group.

Medical observations have shown that viral infections such as COVID-19 can be life-threatening due to an overreaction of the body's immune defense system. Part of the cyclophilin inhibitor class of antivirals, this macrocyclic cyclophilin inhibitor could prove to be a valuable additional therapy to SOC due to its non-immunosuppressive nature.

"New evidence generated by our research group suggests that alisporivir's antiviral activity could work by decreasing the viral load in the cells and reducing the risk of pulmonary damage caused by an excessive immune response from infected patients. The treatment is expected to be most effective in the early stages of infection by inhibiting the virus' capacity to replicate and multiply, potentially due to the drug's capacity to accumulate in the lungs and strong distribution

1. Softic L et al. Inhibition of SARS-CoV-2 infection by the non-immunosuppressive macrocyclic cyclophilin inhibitor Alisporivir (Debio025); Antimicrob Agents Chemother. 2020 Jul; 64(7): e00876-20.

throughout the body overall," **explained Prof. Jean-Michel Pawlotsky, Head of the Biology and Pathology Department at the Henri Mondor Hospital Group.**

"The preliminary evidence provide a scientific rational for this Phase II trial, with hopes that treatment will help patients to avoid advancing to more life-threatening phase of the COVID-19 infection. We are thrilled that this compound will be tested for its ability to fight this pandemic and save lives" **expressed Bertrand Ducrey, CEO of Debiopharm.**

Involved in anti-viral research for over 20 years, Debiopharm has maintained its commitment to fighting cancer and infectious diseases. In addition to its anti-infective alisporivir, the company focuses on developing novel antibiotics to help battle highly-resistant "super-bugs" fueling the growing crisis in antibiotic resistance. Despite the substantial financial responsibility that this COVID-19 trial represents – expected to reach several millions in clinical research and product supply costs - the company has committed to donating all potential commercial revenue to fund research against infectious diseases. If phase II results show the efficacy and safety results required to advance to a larger phase III trial, Debiopharm will seek to partner with a larger global pharmaceutical company or public healthcare organization for rapid and broad patient access.

Debiopharm's commitment to patients

Debiopharm, awarded the Swiss Biotech Success Story 2020, develops innovative therapies targeting high unmet medical needs in oncology and infectious diseases. Bridging the gap between disruptive discovery products and real-world patient reach, we identify high-potential compounds and technologies for in-licensing, clinically demonstrate their safety and efficacy and then select large pharmaceutical commercialization partners to maximize patient access globally.

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