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**Dr. Reddy's and GRA announce Avigan Pivotal Studies Update**  
*Study for hospitalized moderate to severe cases in Kuwait terminated, while study for out-patient mild to moderate cases continues in North America*

Hyderabad, India, January 27, 2021

For Immediate Release

Hyderabad, India, January 27, 2021: Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY along with its subsidiaries together referred to as "Dr. Reddy's") and [Global Response Aid FZCO](#) (GRA) today announced the termination of the Avigan Trial Study conducted in Kuwait focused on moderate to severe COVID-19 patients in a hospital setting.

The hospitalized patient study, conducted in Kuwait, on moderate to severe patients was one of the studies in the overall clinical program for Avigan, spanning the spectrum of asymptomatic to severe cases of COVID-19 in both out-patient and in-patient setting. The Phase-III study, being conducted in an out-patient setting on patients with mild to moderate symptoms in North America by Dr. Reddy's, in partnership with Appili Therapeutics and Global Response Aid, shall continue.

The data from the Kuwait CVD-04-CD-001 study involving moderate to severe COVID-19 hospitalized patients did not show a statistically significant difference for the primary endpoint (i.e., time to sustained hypoxia resolution) for Avigan vs. placebo (7 days vs. 8 days;  $p = >0.05$ ). The full data analysis on 353 subjects would be available by the end of February 2021. Within this group, there was subgroup analysis carried out on 181 patients in the low risk category. The subgroup analysis of the low-risk (low NEWS Score at admission) study cohort ( $n=181$ ) demonstrated a 3 day earlier discharge in the Avigan group compared to the placebo group (8 days vs. 11 days;  $p=0.0063$ ) for time to hospital discharge secondary endpoint. The subgroup analysis data during the initial interim analysis points towards the hypothesis with clinically significant insights from this study that an antiviral drug such as Avigan may be effective as part of early treatment initiation in COVID-19 patients and not effective in the late-stage hospital treatment for moderate and severe COVID-19 patients.

Dr. Reddy's, in partnership with Appili Therapeutics and Global Response Aid, shall continue the Phase III pivotal study [PRESECO] being conducted in North America in an out-patient setting. The PRESECO study aims to determine the efficacy of Avigan as an early treatment for COVID-19 patients with mild to moderate symptoms, with the goal of alleviating symptoms and preventing disease progression before the infection requires hospitalizations or other intensive interventions. Additional observational studies to evaluate the efficacy of Avigan as part of early treatment in COVID-19 patients are also initiated.

Avigan® is a trademark of FUJIFILM Toyama Chemical Co., Ltd.

**About Dr. Reddy's:** Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) is an integrated pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses - Pharmaceutical Services & Active Ingredients, Global Generics and Proprietary Products – Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars and differentiated formulations. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Dr. Reddy's operates in markets across the globe. Our major markets include – USA, India, Russia & CIS countries, and Europe. For more information, log on to: [www.drreddys.com](http://www.drreddys.com)

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**About FUJIFILM Corporation**, Tokyo, Japan is one of the major operating companies of FUJIFILM Holdings Corporation. The company brings cutting edge solutions to a broad range of global industries by leveraging its depth of knowledge and fundamental technologies developed in its relentless pursuit of innovation. Its proprietary core technologies contribute to the various fields including healthcare, graphic systems, highly functional materials, optical devices, digital imaging and document products. These products and services are based on its extensive portfolio of chemical, mechanical, optical, electronic and imaging technologies. For the year ended March 31, 2020, the company had global revenues of \$21 billion, at an exchange rate of 109 yen to the dollar. Fujifilm is committed to responsible environmental stewardship and good corporate citizenship. For more information, please visit: [holdings.fujifilm.com](http://holdings.fujifilm.com)

#### **About Global Response Aid (GRA)**

Agility (KSE/DFM: AGLTY), one of the world's leading logistics companies and AiPharma, an innovative pharma research, development and commercialization company based in Dubai, established Global Response Aid (GRA) to address the market challenges created by the COVID-19 pandemic and other threats to public health. GRA delivers innovative, effective healthcare solutions through a range of pharmaceutical products and technology platforms. It works closely with governments, regulatory authorities, hospitals, clinics, healthcare providers, life sciences companies, NGOs and public institutions to develop strategies that allow them to tackle public health challenges. For more information: [www.globalresponseaid.com](http://www.globalresponseaid.com) [www.agility.com](http://www.agility.com)

#### **About AiPharma**

AiPHARMA is an early-stage biotechnology company with regional offices in Dubai and Tokyo. We take a highly interdisciplinary approach to science, with our services building upon work from leading academic labs in biophysics and algorithmic design that enables the acceleration of life science research and development in the pursuit of improved human health. [For more information: www.aipharmalab.com](http://www.aipharmalab.com)

#### **About Appili Therapeutics**

Appili Therapeutics is an infectious disease biopharmaceutical company that is purposefully built, portfolio-driven, and people-focused to fulfill its mission of solving life-threatening infections. By systematically identifying urgent infections with unmet needs, Appili's goal is to strategically develop a pipeline of novel therapies to prevent deaths and improve lives. As part of a global consortium, Appili is sponsoring late-stage clinical trials evaluating the antiviral Avigan® (favipiravir) for the worldwide treatment and prevention of COVID-19. The Company is also advancing a diverse range of anti-infectives, including a broad-spectrum antifungal, a vaccine candidate to eliminate a serious biological weapon threat, and two novel antibiotic programs. Led by a proven management team, Appili is at the epicenter of the global fight against infection. For more information, visit [www.AppiliTherapeutics.com](http://www.AppiliTherapeutics.com).