

News Release

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Merck KGaA, Darmstadt, Germany, Initiates First Clinical Trial of TLR7 and 8 Inhibitor as a Potential Treatment for Severe Symptoms of Covid-19 Infection

- **Novel mechanism will be studied for the first time to potentially show a reduction in the inflammatory response that can lead to 'cytokine storm' in patients with Covid-19 pneumonia**
- **TLR7 and TLR8 are innate immune sensors that detect single-stranded (ss) RNA from viruses such as SARS-CoV-2**
- **Results from the Phase II study expected by the end of 2020**

Darmstadt, Germany, June 25, 2020– Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced the U.S. Food and Drug Administration (FDA) has cleared its investigational new drug application (IND) for M5049 for the treatment of patients with Covid-19 pneumonia. The Company will initiate a Phase II randomized, controlled clinical study evaluating the safety and efficacy of M5049 in this patient population. M5049 is a potentially first-in-class small molecule that blocks the activation of Toll-like receptor (TLR)7 and TLR8, two innate immune sensors that detect single-stranded (ss) RNA from viruses such as SARS-CoV-2, the virus responsible for Covid-19. Activation of TLR7/8 leads to immune cell activation and inflammation, which when not properly controlled can cause severe immunopathology.

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The aim of the study is to investigate if M5049 intervention at a critical point in the course of Covid-19 disease may prevent or ameliorate the hyper-inflammatory response in patients with Covid-19 pneumonia and prevent progression to 'cytokine storm'. Successful intervention with the investigational drug may reduce life-threatening complications of Covid-19, including severe respiratory symptoms that often necessitate further medical interventions such as mechanical ventilation.

"We have a clear priority to identify potential solutions across the full spectrum of the Covid-19 pandemic, including prevention, symptom management, severe infection and recovery," said Belén Garijo, Member of the Executive Board of Merck KGaA, Darmstadt, Germany, and CEO Healthcare. "With M5049, we aim to study a novel approach to treating severe complications of Covid-19 that we hypothesize could translate to other single-stranded RNA viruses including other coronaviruses."

M5049 will be investigated in a randomized, placebo-controlled study at sites in the United States and Brazil. In addition to standard of care, which may include antiviral treatments, subjects will receive one of two doses of M5049 or placebo with the intent of comparing M5049 to placebo based on patient outcomes. Approximately 150 subjects will be randomized into one of the three treatment arms. In addition to the FDA, Merck KGaA, Darmstadt, Germany, is working with other global health authorities and investigators to accelerate clinical development to meet the critical need presented by the current global pandemic and expects results from the Phase II study around the end of 2020.

M5049 was discovered in-house at Merck KGaA, Darmstadt, Germany, and recently completed a Phase I study in healthy volunteers. The company is evaluating M5049 in immunology indications in addition to a potential therapeutic intervention against Covid-19.

This Phase II study complements the existing response from Merck KGaA, Darmstadt, Germany, to the Covid-19 pandemic, which also includes in-kind contributions, product donations, resources, and expertise in consortia and partnerships aimed at fighting this Covid-19 pandemic. Merck KGaA, Darmstadt, Germany, is dedicated to serving patients, scientists and customers around the globe – for more information on the response, please click [here](#).

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About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across healthcare, life science and performance materials. Around 57,000 employees work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. From advancing gene editing technologies and discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2019, Merck KGaA, Darmstadt, Germany, generated sales of € 16.2 billion in 66 countries.

The company holds the global rights to the name and trademark "Merck" internationally. The only exceptions are the United States and Canada, where the business sectors of Merck KGaA, Darmstadt, Germany operate as EMD Serono in healthcare, MilliporeSigma in life science, and EMD Performance Materials. Since its founding 1668, scientific exploration and responsible entrepreneurship have been key to the company's technological and scientific advances. To this day, the founding family remains the majority owner of the publicly listed company.