

Langen, 13 December 2021

INFORMATION FOR MEDICAL DOCTORS

POSSIBILITY OF TREATING HOSPITALISED COVID-19 PATIENTS UNDER LOW-FLOW OXYGEN TREATMENT WITH CASIRIVIMAB/ **IMDEVIMAB**

The drug Ronapreve (casirivimab/imdevimab), jointly developed by Regeneron/Roche, received marketing authorisation from the European Commission for the prophylaxis and treatment of COVID-19 on 12 November 2021.

Data from a randomised, double-blind, placebo-controlled clinical trial in patients with COVID-19 (symptomatically infected with SARS-CoV-2, detected by RT-gPCR) who did not require supplemental oxygen therapy was the basis for the marketing authorisation of Ronapreve. The indication reads: "treatment of coronavirus 2019 disease (COVID-19) in adults and adolescents aged 12 years and older with at least 40 kg body weight who do not require supplemental oxygen therapy and who are at increased risk for a severe course of COVID-19". The indication also includes hospitalised and/or IgG-seronegative patients.

The indication for low-flow oxygen therapy is usually quite broad and not necessarily related to COVID-19 disease. Therefore, these patients can also be treated at the doctor's discretion and efficacy can be assumed.

