Brand Name: Ronapreve
Generic: casirivimab and imdevimab
Type: monoclonal antibody
Year Accepted/Phase: 2020

Mechanism:

Casirivimab and imdevimab are monoclonal antibodies that bind to different parts of the spike protein of SARS-CoV-2, blocking the virus from attaching to and entering human cells.

Chemical Structure: N/A

Indication:

Ronapreve is indicated for the treatment of mild to moderate COVID-19 in non-hospitalized patients at high risk for progressing to severe disease, and for prophylaxis in individuals at high risk of exposure.

Clinical trials:

Phase I/II Trials
Purpose: Assess the safety, tolerability, and initial efficacy of Ronapreve in non-hospitalized patients with COVID-19.
Dates: Conducted in mid-2020.
Results: The trials demonstrated that Ronapreve was well-tolerated with a favorable safety profile. Preliminary efficacy data suggested a reduction in viral load and symptom improvement in patients treated with Ronapreve compared to placebo.
Impact: These early results provided the foundation for larger Phase III trials.

Phase III Trials (Outpatients)
Purpose: Evaluate the efficacy and safety of Ronapreve in preventing hospitalization and death in non-hospitalized patients with COVID-19.
Dates: Conducted from late 2020 to early 2021.
Results: The Phase III trials showed that Ronapreve significantly reduced the risk of hospitalization or death by about 70% in non-hospitalized patients with COVID-19 compared to placebo. The combination therapy also reduced the duration of symptoms and viral load.
Impact: These results led to emergency use authorizations (EUAs) and approvals in various countries, including the FDA EUA in November 2020.

Phase III Trials (Hospitalized Patients)
Purpose: Assess the efficacy and safety of Ronapreve in hospitalized patients with COVID-19.
Dates: Conducted in 2021.
Results: In hospitalized patients who were seronegative (i.e., had not yet developed their own antibodies against the virus), Ronapreve reduced the risk of death and the need for mechanical ventilation. However, in seropositive patients, the benefit was not as pronounced.
Impact: These findings helped refine the use of Ronapreve in different patient populations and clinical settings.

Prevention Trials
Purpose: Evaluate the efficacy of Ronapreve in preventing COVID-19 infection in household contacts of infected individuals.
Dates: Conducted in early 2021.
Results: The trials showed that Ronapreve was effective in reducing the risk of symptomatic COVID-19 infection in household contacts by over 80%.
Impact: This supported the use of Ronapreve as a prophylactic treatment for individuals at high risk of exposure to the virus.