ForPatients
by Roche

COVID-19 Pneumonia

A study to find out if a new medicine (either astegolimab or efmarodocokin alfa) was safe and effective in patients with severe COVID-19 pneumonia

A Study to Evaluate the Safety and Efficacy of MSTT1041A (Astegolimab) or UTTR1147A in Patients With Severe COVID-19 Pneumonia

Trial Status	Trial Runs In	Trial Identifier
Completed	4 Countries	NCT04386616 GA42469

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase II, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Safety and Efficacy of MSTT1041A or UTTR1147A in Patients With Severe COVID-19 Pneumonia

Trial Summary:

This is a Phase II, randomized, double-blind, placebo-controlled, multicenter study to assess the efficacy and safety of MSTT1041A (astegolimab) compared with placebo and of UTTR1147A compared with placebo, in combination with standard of care (SOC), in patients hospitalized with severe coronavirus disease 2019 (COVID-19) pneumonia.

Genentech, Inc. Sponsor	**Phase 2** Phase

NCT04386616 GA42469
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

This clinical trial was done to study two new medicines called, astegolimab” and “efmarodocokin alfa”, for the treatment of patients with severe COVID-19 pneumonia. This study was done to find out if either medicine was effective and safe for treating patients

with severe COVID-19 pneumonia in comparison to placebo treatments. There were 396 patients who took part in this study at 54 study centers in 4 countries.

Inclusion Criteria:

- Hospitalized with COVID-19 pneumonia confirmed per WHO criteria (including a positive PCR of any specimen; e.g., respiratory, blood, urine, stool, other bodily fluid) and evidenced by chest X-ray or CT scan
- Peripheral capillary oxygen saturation (SpO2) #93% (on room air or supplemental oxygen) or partial pressure of oxygen (PaO2)/fraction of inspired oxygen (FiO2) #300 millimetres of mercury (mmHg) or requiring supplemental oxygen to maintain SpO2 >93% or requirement for supplemental oxygen to maintain SpO2 at an acceptable level per local standard of care

Exclusion Criteria:

- Pregnant or breastfeeding, or positive pregnancy test at screening
- Any serious medical condition or abnormality of clinical laboratory tests that, in the investigator's judgment, precludes the patient's safe participation in and completion of the study
- In the opinion of the investigator, progression to death is imminent and inevitable within the next 24 hours, irrespective of the provision of treatments
- Participating in another clinical drug trial
- Treatment with investigational therapy (other than for COVID-19) within 5 half-lives or 30 days (whichever is longer) prior to initiation of study drug
- Use of Janus kinase (JAK) inhibitor within 30 days or 5 drug elimination half-lives (whichever is longer) prior to screening
- Have received high-dose systemic corticosteroids (#1 mg/kg/day methylprednisolone or equivalent) within 72 hours prior to Day 1
- Known HIV infection with CD4 <200 cells/microlitre (uL) or <14% of all lymphocytes
- ALT or AST >10 times the upper limit of normal (ULN) detected at screening
- History of anaplastic large-cell lymphoma or mantle-cell lymphoma
- History of cancer within the previous 5 years unless it has been adequately treated and considered cured or remission-free in the investigator's judgment
- Clinical evidence of active or unstable cardiovascular disease (e.g., acute myocardial ischemia or decompensated heart failure), as determined by investigator assessment, ECG, laboratory assessment, or echocardiographic data
- History of moderate or severe allergic, anaphylactic, or anaphylactoid reactions or hypersensitivity to any component of study treatment