

## Report Overview - GB-MHRA-ESUSAR-215840423001-00109843

## Submission Details

- Submitted by: Prof Richard Haynes
- Submission date: 19/05/2021

## 1. Trial Information

- Reference: RECOVERY SUSAR 010
- Trial Name: 2020-001113-21 RECOVERY - Randomised Evaluation of COVID-19 Therapy

## 2. Patient Details

- Patient gender: Female
- Patient age at time of the side effect: 77 Years
- Patient Identification Number: 1216393

## 3. Suspect Reactions

Date sponsor was made aware of the SUSAR:  
23/12/2020

Country of Origin:  
United Kingdom

## Narrative:

78 year old lady admitted with COVID-19 on 21-Dec-2021. Provided consent for RECOVERY and allocated to receive REGN-COV2 and aspirin. Received both treatments; REGN-COV2 infusion on 22-Dec-21. On 22-Dec-21 desaturated with increasing oxygen requirement. Differential diagnosis included pulmonary embolism, progression of COVID-19, allergic reaction to REGN-COV2 or antibody-dependent enhancement of disease. Investigator's final opinion was that progression of COVID-19 was most likely, but as antibody-dependent enhancement could not be excluded MHRA instructed that it be reported as a SUSAR.

## Seriousness

- Life threatening

## Hypoxia

- Reaction Outcome: Recovered
- Start date: 21/12/2020

## Chest X-ray

- Result: COVID-19
- Test date: 21/12/2020

#### 4. Suspect Medicines

##### casirivimab+imdevimab

‣ Drug Characterisation:	Suspect
‣ Drug Dosage:	8 G gram(s)
‣ Drug Dosage Interval:	1 Hours
‣ Form:	Intravenous infusion
‣ Route of Administration:	Intravenous (not otherwise specified)
‣ Indication:	COVID-19
‣ Start date:	21/12/2020
‣ Action Taken:	Not applicable

##### CHLORPHENAMINE

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	10 Mg milligram(s)
‣ Drug Dosage Interval:	1 Hours
‣ Form:	Intravenous infusion
‣ Route of Administration:	Intravenous bolus
‣ Indication:	Acute allergic reaction
‣ Start date:	22/12/2020
‣ Action Taken:	Not applicable

##### DALTEPARIN

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	18000 Iu international unit(s)
‣ Drug Dosage Interval:	1 Days
‣ Form:	Injection
‣ Route of Administration:	Subcutaneous
‣ Indication:	Pulmonary embolism
‣ Start date:	22/12/2020
‣ Action Taken:	Not applicable

##### HYDROCORTISON

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	100 Mg milligram(s)
‣ Drug Dosage Interval:	1 Days
‣ Form:	Injection
‣ Route of Administration:	Intravenous bolus
‣ Indication:	Acute allergic reaction
‣ Start date:	22/12/2020
‣ Action Taken:	Not applicable

#### 5. Causality Assessment

##### casirivimab+imdevimab - Hypoxia

‣ Assessment by sponsor:	No reasonable possibility
‣ Assessment by investigator:	Reasonable possibility