

## Report Overview - GB-MHRA-ESUSAR-215840423001-00107862

## Submission Details

- Submitted by: Prof Richard Haynes
- Submission date: 21/12/2020

## 1. Trial Information

- 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: 72 Years
- Patient Identification Number: 1211335

## Chronic obstructive pulmonary disease

- Start date: 01/01/2010
- Continuing: Yes

## 3. Suspect Reactions

Date sponsor was made aware of the SUSAR:  
18/12/2020

Country of Origin:  
United Kingdom

## Narrative:

72 year old care home resident with chronic obstructive pulmonary disease on long-term oxygen therapy admitted with increasing shortness of breath, COVID-19 and type 2 resp failure on 16-Dec-2020. Went onto bilevel positive airway pressure ventilation and dexamethasone and antibiotics. Was randomised on 17-Dec-2020 to REGN-COV2 mAb and started the infusion on 18-Dec-2020 at 16:05h. 2-3 mins after the infusion started the patient felt unwell with increasing dyspnoea, cough, flushing and palpitations, and the infusion was stopped shortly afterwards. The doctor assessing her found no oedema or other features of angioedema or anaphylaxis. She was mildly flushed, chest signs unchanged and oxygenation/respiratory rate also unchanged. She was prescribed chlorpheniramine. There was no subsequent change in vital signs and she felt better around 30-60 mins later. The infusion was not restarted. She remains in hospital on treatment for COVID-19 and type 2 respiratory failure.

## Seriousness

- Other

## Acute allergic reaction

- Reaction Outcome: Recovered

‣ Start date:	18/12/2020
‣ End date:	18/12/2020

#### 4. Suspect Medicines

##### Casirivimab + imdevimab

‣ Drug Characterisation:	Suspect
‣ Drug Dosage:	8 G gram(s)
‣ Drug Dosage Interval:	1 Days
‣ Form:	Intravenous infusion
‣ Route of Administration:	Intravenous drip
‣ Indication:	Viral pneumonia
‣ Start date:	18/12/2020
‣ End date:	18/12/2020
‣ Action Taken:	Drug withdrawn

##### FERROUS SULPHATE

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	200 Mg milligram(s)
‣ Drug Dosage Interval:	8 Hours
‣ Form:	Tablet
‣ Route of Administration:	Oral
‣ Indication:	Anaemia iron deficiency
‣ Start date:	16/12/2020
‣ Action Taken:	Not applicable

##### LANSOPRAZOL

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	15 Mg milligram(s)
‣ Drug Dosage Interval:	12 Hours
‣ Form:	Tablet
‣ Route of Administration:	Oral
‣ Indication:	Gastroesophagitis
‣ Start date:	16/12/2020
‣ Action Taken:	Not applicable

##### PREGABALIN

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	150 Mg milligram(s)
‣ Drug Dosage Interval:	12 Hours
‣ Form:	Tablet
‣ Route of Administration:	Oral
‣ Indication:	Chronic pain
‣ Start date:	16/12/2020
‣ Action Taken:	Not applicable

##### CARBOCYSTEINE

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	750 Mg milligram(s)
‣ Drug Dosage Interval:	12 Hours
‣ Form:	Tablet
‣ Route of Administration:	Oral
‣ Indication:	Chronic obstructive pulmonary disease
‣ Start date:	16/12/2020

‣ Action Taken: Not applicable

#### CLOPIDOGREL

‣ Drug Characterisation: Concomitant  
‣ Drug Dosage: 75 Mg milligram(s)  
‣ Drug Dosage Interval: 1 Days  
‣ Form: Tablet  
‣ Route of Administration: Oral  
‣ Indication: Atherosclerotic cardiovascular disease  
‣ Start date: 16/12/2020  
‣ Action Taken: Not applicable

#### CO-AMOXICLAV

‣ Drug Characterisation: Concomitant  
‣ Drug Dosage: 625 Mg milligram(s)  
‣ Drug Dosage Interval: 8 Hours  
‣ Form: Tablet  
‣ Route of Administration: Oral  
‣ Indication: Acute pneumonia  
‣ Start date: 16/12/2020  
‣ Action Taken: Not applicable

#### BUMETANIDE

‣ Drug Characterisation: Concomitant  
‣ Drug Dosage: 4 Mg milligram(s)  
‣ Drug Dosage Interval: 1 Days  
‣ Form: Tablet  
‣ Route of Administration: Oral  
‣ Indication: Oedema  
‣ Start date: 16/12/2020  
‣ Action Taken: Not applicable

#### FOSTAIR

‣ Drug Characterisation: Concomitant  
‣ Drug Dosage: µg microgram(s)  
‣ Drug Dosage Interval: 12 Hours  
‣ Form: Inhalation powder, pre-dispensed  
‣ Route of Administration: Oral  
‣ Indication: Chronic obstructive pulmonary disease  
‣ Start date: 16/12/2020  
‣ Action Taken: Not applicable

#### IPRATROPIUM BROMIDE

‣ Drug Characterisation: Concomitant  
‣ Drug Dosage: 500 µg microgram(s)  
‣ Drug Dosage Interval: 12 Hours  
‣ Form: Nebuliser solution  
‣ Route of Administration: Oral  
‣ Indication: Chronic obstructive pulmonary disease  
‣ Start date: 16/12/2020  
‣ Action Taken: Not applicable

#### SALBUTAMOL

‣ Drug Characterisation: Concomitant  
‣ Drug Dosage: 2.5 Mg milligram(s)  
‣ Drug Dosage Interval: 6 Hours

▸ Form:	Nebuliser solution
▸ Route of Administration:	Oral
▸ Indication:	Chronic obstructive pulmonary disease
▸ Start date:	16/12/2020
▸ Action Taken:	Not applicable

## 5. Causality Assessment

### Casirivimab + imdevimab - Acute allergic reaction

▸ Assessment by sponsor:	Reasonable possibility
▸ Assessment by investigator:	Reasonable possibility