eSUSAR

MHRA

Report Overview - GB-MHRA-ESUSAR-215840423001-00106638

Submission Details

- **Submitted by:** Prof Richard Haynes
- **Submission date:** 17/06/2020

1. Trial Information

- **Reference:** RECOVERY SUSAR 002
- **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:** 1098515

Obstructive sleep apnea syndrome

- **Continuing:** Yes

Chronic obstructive pulmonary disease

- **Continuing:** Yes

Depression

- **Continuing:** Yes

Hiatus hernia

- **Continuing:** Yes

3. Suspect Reactions

Date sponsor was made aware of the SUSAR:
09/06/2020

Country of Origin:
United Kingdom

Narrative:
Participant presented to A&E on 10 May 2020 with abdominal pain and vomiting following discharge from intermediate care facility 1 week previously. She was started on antibiotics for suspected diverticulitis however she was reviewed by the surgical team who had no concerns about her. She had a dry cough and shortness of breath for several days with a positive COVID swab. On 13 May 2020 she was recruited into RECOVERY and assigned

hydroxychloroquine. On 15 May 2020 she was randomised in the trial's second randomisation and received tocilizumab 400 mg tocilizumab on 15 May and 16 May 2020. She was transferred to ICU for a trial of CPAP and was then transferred back to the ward where she continued to improve and was discharged on 28 May 2020. Participant re-admitted 07 Jun 2020 with right ear pain and facial swelling. She was commenced on IV co-amoxiclav and gentisone drops. ENT reviewed her and a CT head and neck was performed. This showed right sided otitis externa with soft tissue involvement. No associated bone loss or abscess. Partly imaged lung changes in keeping with known Covid19 infection. Participant remained well during her admission and her symptoms began to resolve with treatment. On 10 Jun 2020 she was stepped down to oral antibiotics. She was seen in ENT CAS clinic where debris in the right ear was cleaned out. She was discharged from their service and completed a course of gentisone drops. She was discharged home on 12 May 2020.

Seriousness

- Hospitalisation

Otitis externa

- **Reaction Outcome:** Recovered
- **Start date:** 07/06/2020
- **End date:** 12/06/2020

Computerised tomogram head abnormal

- **Result:** Otitis externa with soft tissue involvement.
- **Test date:** 07/06/2020

4. Suspect Medicines

ATORVASTATIN CALCIUM

- **Drug Characterisation:** Concomitant
- **Drug Dosage:** 20 Mg milligram(s)
- **Drug Dosage Interval:** 1 Days
- **Form:** Tablet
- **Route of Administration:** Oral
- **Indication:** Cardiovascular risk
- **Start date:** 01/01/2020
- **Action Taken:** Not applicable

BUPRENORPHIN

- **Drug Characterisation:** Concomitant
- **Drug Dosage:** 5 µg microgram(s)
- **Drug Dosage Interval:** 1 Hours
- **Form:** Cutaneous patch
- **Route of Administration:** Transdermal
- **Indication:** Pain
- **Start date:** 01/01/2020
- **Action Taken:** Not applicable

VENLAFAXIN

- **Drug Characterisation:** Concomitant
- **Drug Dosage:** 112.5 Mg milligram(s)
- **Drug Dosage Interval:** 1 Days
- **Form:** Tablet
- **Route of Administration:** Oral
- **Indication:** Depression
- **Start date:** 01/01/2020
- **Action Taken:** Not applicable

COLECALCIFEROL

- **Drug Characterisation:** Concomitant
- **Drug Dosage:** 800 Iu international unit(s)
- **Drug Dosage Interval:** 1 Days
- **Form:** Tablet
- **Route of Administration:** Oral
- **Indication:** Osteopenia
- **Start date:** 01/01/2020
- **Action Taken:** Not applicable

OMEPRAZOL

- **Drug Characterisation:** Concomitant
- **Drug Dosage:** 20 Mg milligram(s)
- **Drug Dosage Interval:** 1 Days
- **Form:** Tablet
- **Route of Administration:** Oral
- **Indication:** Hiatus hernia
- **Start date:** 01/01/2020
- **Action Taken:** Not applicable

RIVAROXABAN

- **Drug Characterisation:** Concomitant
- **Drug Dosage:** 10 Mg milligram(s)
- **Drug Dosage Interval:** 1 Days
- **Form:** Tablet
- **Route of Administration:** Oral
- **Indication:** VTE prophylaxis
- **Start date:** 28/05/2020
- **Action Taken:** Not applicable

TOCILIZUMAB

- **Drug Characterisation:** Suspect
- **Drug Dosage:** 400 Mg milligram(s)
- **Drug Dosage Interval:** 1 Days
- **Form:** Intravenous infusion
- **Route of Administration:** Intravenous (not otherwise specified)
- **Indication:** Viral pneumonia
- **Start date:** 13/05/2020
- **End date:** 14/05/2020
- **Action Taken:** Not applicable

HYDROXYCHLOROQUINE SULFATE

- **Drug Characterisation:** Concomitant
- **Drug Dosage:** 400 Mg milligram(s)
- **Drug Dosage Interval:** 12 Hours
- **Form:** Tablet
- **Route of Administration:** Oral
- **Indication:** Viral pneumonia
- **Start date:** 13/05/2020
- **End date:** 22/05/2020

- **Action Taken:** Not applicable

5. Causality Assessment

TOCILIZUMAB - Otitis externa

- **Assessment by sponsor:** Reasonable possibility
- **Assessment by investigator:** Reasonable possibility