

## Report Overview - GB-MHRA-ESUSAR-215840423001-00111023

## Submission Details

- Submitted by: Prof Richard Haynes  
▸ Submission date: 21/09/2021

## 1. Trial Information

- Reference: RECOVERY SUSAR 017  
▸ 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: 73 Years  
▸ Patient Identification Number: 1427797

## Rheumatoid arthritis

- Continuing: Yes

## Chronic kidney disease stage 3

- Continuing: Yes

## Polymyalgia rheumatica

- Continuing: Yes

## Haemochromatosis

- Continuing: Yes

## Diverticular disease

- Continuing: Yes

## Kyphoscoliosis

- Continuing: Yes

## Spinal stenosis

- Continuing: Yes

## RITUXIMAB

- Start date: 04/2021

### 3. Suspect Reactions

**Date sponsor was made aware of the SUSAR:**

20/09/2021

**Country of Origin:**

United Kingdom

**Narrative:**

Admitted on 05/09/21 with shortness of breath, fever, cough and hypoxia with positive SARS-CoV-2 PCR in community. Regular prednisolone and hydroxychloroquine stopped on admission. Treated with dexamethasone and amoxicillin and randomised within RECOVERY to receive baricitinib on 06/09/21. By 11/09/21, developed worsening respiratory failure with increased CRP. CT imaging showed dense consolidation as well as small foci of cavitation in left lower lobe. Initially treated as presumed bacterial pneumonia with Tazocin and then vancomycin and ceftazidime. Baricitinib stopped. Later a positive beta-D-glucan result and sputum microscopy showing filamentous fungi, suggested a possible fungal component to the pneumonia. Sputum culture grew *Pseudomonas aeruginosa*, fungal culture negative. Voriconazole added to treatment. Patient continued to deteriorate and died from respiratory failure on 19/09/21. Initial trial suspected serious adverse reaction reported on 15/09/21, but considered expected as presumed bacterial pneumonia (present on SmPC). However, following diagnosis of fungal involvement and fatal outcome, amended to unexpected hence this SUSAR report..

**Seriousness**

▸ Death

**Date of Death:**

19/09/2021

**Pneumonia fungal**

▸ Reaction Outcome: Fatal  
▸ Start date: 11/09/2021

**Fungus sputum test positive**

▸ Result: Microscopy: Filamentous fungi

**Sputum culture**

▸ Result: *Pseudomonas aeruginosa*. Fungal culture negative

**Chest CT**

▸ Result: Small foci of cavitation in left lower lobe

### 4. Suspect Medicines

**PREDNISOLONE**

▸ Drug Characterisation: Concomitant  
▸ Drug Dosage: 12.5 Mg milligram(s)  
▸ Drug Dosage Interval: 1 Days  
▸ Form: Tablet  
▸ Route of Administration: Oral  
▸ Indication: Rheumatoid arthritis  
▸ End date: 05/09/2021  
▸ Action Taken: Drug withdrawn

**HYDROXYCHLOROQUINE**

‣ Drug Characterisation: Concomitant  
‣ Drug Dosage: 200 Mg milligram(s)  
‣ Drug Dosage Interval: 1 Days  
‣ Form: Tablet  
‣ Route of Administration: Oral  
‣ Indication: Rheumatoid arthritis  
‣ End date: 05/09/2021  
‣ Action Taken: Drug withdrawn

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#### BARICITINIB

‣ Drug Characterisation: Suspect  
‣ Drug Dosage: 4 Mg milligram(s)  
‣ Drug Dosage Interval: 1 Days  
‣ Form: Tablet  
‣ Route of Administration: Oral  
‣ Indication: COVID-19  
‣ Start date: 06/09/2021  
‣ End date: 11/09/2021  
‣ Action Taken: Drug withdrawn

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#### DEXAMETHASONE

‣ Drug Characterisation: Concomitant  
‣ Drug Dosage: 6 Mg milligram(s)  
‣ Drug Dosage Interval: 1 Days  
‣ Form: Tablet  
‣ Route of Administration: Oral  
‣ Indication: COVID-19  
‣ Start date: 05/09/2021  
‣ End date: 10/09/2021  
‣ Action Taken: Not applicable

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#### AMOXICILLIN

‣ Drug Characterisation: Concomitant  
‣ Drug Dosage: 500 Mg milligram(s)  
‣ Drug Dosage Interval: 8 Hours  
‣ Form: Tablet  
‣ Route of Administration: Oral  
‣ Indication: Lower respiratory tract infection  
‣ Start date: 05/09/2021  
‣ End date: 08/09/2021  
‣ Action Taken: Not applicable

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#### TAZOCIN

‣ Drug Characterisation: Concomitant  
‣ Drug Dosage: 4.5 G gram(s)  
‣ Drug Dosage Interval: 8 Hours  
‣ Form: Intravenous infusion  
‣ Route of Administration: Intravenous (not otherwise specified)  
‣ Indication: Pneumonia  
‣ Start date: 08/09/2021  
‣ End date: 15/09/2021  
‣ Action Taken: Not applicable

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#### VANCOMYCIN

‣ Drug Characterisation: Concomitant  
‣ Drug Dosage: 15 mg/kg milligram(s)/kilogram  
‣ Drug Dosage Interval: 12 Hours

- Form: Intravenous infusion
- Route of Administration: Intravenous (not otherwise specified)
- Indication: Pneumonia
- Start date: 15/09/2021
- Action Taken: Not applicable

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#### CEFTAZIDIME

- Drug Characterisation: Concomitant
- Drug Dosage: 2 G gram(s)
- Drug Dosage Interval: 8 Hours
- Form: Intravenous infusion
- Route of Administration: Intravenous (not otherwise specified)
- Indication: Pneumonia
- Start date: 15/09/2021
- Action Taken: Not applicable

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#### VORICONAZOLE

- Drug Characterisation: Concomitant
- Drug Dosage: 200 Mg milligram(s)
- Drug Dosage Interval: 12 Hours
- Form: Tablet
- Route of Administration: Oral
- Indication: Pneumonia fungal
- Start date: 17/09/2021
- Action Taken: Not applicable

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#### DEXAMETHASONE

- Drug Characterisation: Concomitant
- Drug Dosage: 12 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: COVID-19
- Start date: 10/09/2021
- Action Taken: Not applicable

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#### OMEPRAZOLE

- Drug Characterisation: Concomitant
- Drug Dosage: 40 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: Gastroprotection
- Start date: 05/09/2021
- Action Taken: Not applicable

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#### FUROSEMIDE

- Drug Characterisation: Concomitant
- Drug Dosage: 40 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Action Taken: Not applicable

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#### AMLODIPINE

- Drug Characterisation: Concomitant

- Drug Dosage: 10 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Action Taken: Not applicable

#### ADCAL-D3

- Drug Characterisation: Concomitant
- Drug Dosage: 1 DF dosage form
- Drug Dosage Interval: 12 Hours
- Form: Tablet
- Route of Administration: Oral
- Action Taken: Not applicable

#### RISEDRONATE

- Drug Characterisation: Concomitant
- Drug Dosage: 35 Mg milligram(s)
- Drug Dosage Interval: 1 Weeks
- Form: Tablet
- Route of Administration: Oral
- Action Taken: Not applicable

#### CLARITHROMYCIN

- Drug Characterisation: Concomitant
- Drug Dosage: 500 Mg milligram(s)
- Drug Dosage Interval: 12 Hours
- Form: Tablet
- Route of Administration: Oral
- Indication: Pneumonia
- Start date: 11/09/2021
- End date: 15/09/2021
- Action Taken: Not applicable

### 5. Causality Assessment

#### BARICITINIB - Pneumonia fungal

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