

Report Overview - GB-MHRA-ESUSAR-215840423001-00110509

Submission Details

- Submitted by: Prof Richard Haynes
- Submission date: 28/07/2021

1. Trial Information

- Reference: SUSAR 015
- Trial Name: 2020-001113-21 RECOVERY - Randomised Evaluation of COVID-19 Therapy

2. Patient Details

- Patient gender: Male
- Patient age at time of the side effect: 38 Years
- Patient Identification Number: 1402290

Asthma

- Continuing: Yes

3. Suspect Reactions

Date sponsor was made aware of the SUSAR:
16/07/2021

Country of Origin:
United Kingdom

Narrative:

pulmonary embolism and bilateral cavitating pneumonia with lung abscess. Immune Suppressive secondary to Baricitinib may have caused increased of developing cavitating pneumonia. Patient was also treated with tocilizumab and dexamethasone during his admission with covid Pneumonitis, and these treatments will also contribute to the immune suppression.

Seriousness

- Hospitalisation

Lung abscess

- Reaction Outcome: Not Recovered
- Start date: 15/07/2021

Computerised tomography abnormal

- ▶ **Result:** Large thick walled cavity in the right lower lobe
- ▶ **Test date:** 15/07/2021

4. Suspect Medicines

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:** 29/06/2021
- ▶ **End date:** 30/06/2021
- ▶ **Action Taken:** Drug withdrawn

PIPERACILLIN and TAZOBACTAM

- ▶ **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:** Abscess
- ▶ **Start date:** 15/07/2021
- ▶ **Action Taken:** Not applicable

BECLOMETASONE

- ▶ **Drug Characterisation:** Concomitant
- ▶ **Drug Dosage:** 200 Mg milligram(s)
- ▶ **Drug Dosage Interval:** 12 Hours
- ▶ **Form:** Pressurised inhalation
- ▶ **Route of Administration:** Other
- ▶ **Start date:** 15/07/2021
- ▶ **Action Taken:** Not applicable

PARACETAMOL

- ▶ **Drug Characterisation:** Concomitant
- ▶ **Drug Dosage:** 1 G gram(s)
- ▶ **Drug Dosage Interval:** 6 Hours
- ▶ **Form:** Tablet
- ▶ **Route of Administration:** Oral
- ▶ **Start date:** 15/07/2021
- ▶ **Action Taken:** Not applicable

APIXABAN

- ▶ **Drug Characterisation:** Concomitant
- ▶ **Drug Dosage:** 10 Mg milligram(s)
- ▶ **Drug Dosage Interval:** 12 Hours
- ▶ **Form:** Tablet
- ▶ **Route of Administration:** Oral
- ▶ **Indication:** Anticoagulant therapy
- ▶ **Start date:** 15/07/2021

▸ Action Taken:

Not applicable

5. Causality Assessment

Baricitinib - Lung abscess

▸ Assessment by sponsor: Reasonable possibility

▸ Assessment by investigator: Reasonable possibility