



ECUSTEC Treatment Form 1

TO BE COMPLETED FROM THE CASE NOTES ON OR AFTER DAY OF 1ST DOSE OF TRIAL TREATMENT

Trial Number: Site Name: _____ Date of Birth: ___/___/___ (mon/yyyy)

Part A: Treatment Details

Date of 1st dose of trial treatment: ___/___/___ (dd/mon/yyyy)

Time of treatment: : (24 hour clock)

Full dose given?: Yes No*

*If no: Expected dose ml Received dose ml

When full dose not given, why?: Immunogenicity Infusion Reaction Extravasation Other*

*If other, reason: _____

Part B: Clinical Details

Closest eGFR prior to 1st treatment dose: . ml/min/1.73m² Date: (dd/mon/yyyy)
(using the Schwartz formula (protocol section 5))

Part C: Plasma Exchange Therapy (Since randomisation and prior to first trial treatment dose.)

Patients should NOT receive plasma exchange therapy

Did the patient have **plasma exchange** (PE)? Yes* No

*If yes, how many exchanges?

1st Plasma Exchange Start date: (dd/mon/yyyy) Stop date: (dd/mon/yyyy)

2nd Plasma Exchange Start date: (dd/mon/yyyy) Stop date: (dd/mon/yyyy)

3rd Plasma Exchange Start date: (dd/mon/yyyy) Stop date: (dd/mon/yyyy)

Part D: Infusions and Supportive Treatment (Since randomisation and prior to first trial treatment dose.)

Did the patient have a **plasma** infusion? Yes* No

*If yes, how many infusions?

Infusion 1 volume ml Start date: (dd/mon/yyyy) Time of Treatment : (24 hour clock)

Infusion 2 volume ml Start date: (dd/mon/yyyy) Time of Treatment : (24 hour clock)

Infusion 3 volume ml Start date: (dd/mon/yyyy) Time of Treatment : (24 hour clock)

Part E: Willing to continue

Has the patient/parent confirmed willingness to continue? Yes No*

*If no, please complete an Exit Form

Part F: Form Completion

Completed by (name): _____

Signed: _____ Date Completed: (dd/mon/yyyy)

PI Name: _____

PI Confirmation Signature: _____ Date Completed: (dd/mon/yyyy)