GREAT-2 Worksheet – Visit 2 Baseline & Randomisation

16. Date of Visit 2

16.1 Date of Visit 2 [ ] [ ] [ ] (dd-mm-yyyy)

Visit 2 must be within 35 days of visit 1.

17. Pregnancy Test - Serum

Tick NA for male participants and female participants who are permanently sterile or post-menopausal

17.1 Has serum pregnancy test been performed at screening? ○ Yes ○ No ○ NA

Female participants who are not permanently sterile or post-menopausal should have a pregnancy test

17.3.1 Date of Pregnancy Test [ ] [ ] [ ] (dd-mm-yyyy)

17.3.3 Result of Pregnancy Test ○ Positive ○ Negative

18. Pregnancy Test – Urine

18.1 Has urine pregnancy test been performed on day of visit? ○ Yes ○ No ○ NA

Female participants who are not permanently sterile or post-menopausal should have a pregnancy test

18.3.1 Result of Pregnancy Test ○ Positive ○ Negative

If positive - Pregnancy is an exclusion criteria, please withdraw the participant

19. Sputum sample for *P.aeruginosa* testing

19.1 Result of sputum sample for *P. aeruginosa* taken during screening period ○ Positive ○ Negative

If Negative - Participant not eligible to take part in the trial

20. Blood Tests Reviewed

20.1	Have blood tests taken at screening been reviewed by a doctor? (Must be **YES** before continuing)	○ Yes ○ No

21. Inclusion Criteria

21.1	Age 18-85	○ Yes ○ No
21.2	Clinical diagnosis of Bronchiectasis	○ Yes ○ No
21.3	Able to and provided informed consent	○ Yes ○ No
21.4	Previous computerised tomography (CT) scan of the chest demonstrating bronchiectasis in 1 or more lobes	○ Yes ○ No
21.5	A sputum sample that is culture or PCR positive for *P. aeruginosa* sent at the screening visit, within 35 days of randomisation*† (**If No** - Participant not eligible to take part in the trial)	○ Yes ○ No
21.6	*P. aeruginosa* in sputum, bronchoalveolar lavage or another airway sample at least once in the 24 months prior to screening* (**If No** see Q21.6.1)	○ Yes ○ No
21.6.1	Has a further sample, positive for *P. aeruginosa*, been obtained during the 35-day screening period? There must be at least 21 days between this sample and the sample obtained at the screening visit.	○ Yes ○ No

*a participant who does not have a previous positive sample for *P. aeruginosa* may submit two samples, at least 21 days apart, during the 35-day screening period. If these samples are both positive for *P. aeruginosa* then inclusion criteria 5 and 6 will be deemed met and the participant may be enrolled.

† repeat sputum samples may be provided during the screening period, if the sample taken during the screening visit is negative for P. aeruginosa

22. Exclusion Criteria

22.1	Known hypersensitivity to Gremubamab or any excipient of the investigational product	○ Yes ○ No
22.2	Known clinical diagnosis of Cystic fibrosis	○ Yes ○ No
22.3	Immunodeficiency requiring replacement immunoglobulin	○ Yes ○ No
22.4	Active tuberculosis or nontuberculous mycobacterial infection (currently undertreatment, or requiring treatment in the opinion of the investigator).	○ Yes ○ No
22.5	Active allergic bronchopulmonary aspergillosis (receiving treatment with corticosteroids and/or antifungal medication)	○ Yes ○ No
22.6	Recent significant haemoptysis (a volume requiring clinical intervention, within the previous 4 weeks prior to screening)	○ Yes ○ No
22.7	Treatment with long term inhaled, systemic or nebulized anti- pseudomonal antibiotics which are newly initiated within the previous 3 months prior to screening (a)	○ Yes ○ No
22.8	Chronic treatment with cyclical doses of inhaled or nebulized antibiotics e.g. 28 days on and 28 days off at the time of screening	○ Yes ○ No
22.9	Receipt of antipseudomonal antibiotics for an exacerbation during the screening period (b)	○ Yes ○ No
22.10	Treatment with immunosuppressives within previous 6 months prior to screening	○ Yes ○ No
22.11	Participants with a primary diagnosis of Chronic obstructive pulmonary disease (COPD) associated with >10 pack years smoking history (c)	○ Yes ○ No
22.12	Participants with a primary diagnosis of asthma or asthma which is considered to be poorly controlled at screening (c)	○ Yes ○ No
22.13	Participants with FEV1 <25% predicted value at screening	○ Yes ○ No

22.14	Glomerular filtration rate (eGFR) below 25ml/min/1.73m2 or requiring dialysis. This will be determined at screening (If Yes - Participant not eligible to take part in the trial)	○ Yes ○ No
22.15	Use of any investigational drugs within five times of the elimination half-life after the last dose or within 30 days, whichever is longer	○ Yes ○ No
22.16	Unstable co-morbidities (e.g. cardiovascular disease, active malignancy) which in the opinion of the investigator would make participation in the trial not in the participant's best interest	○ Yes ○ No
22.17	Pregnant or lactating females	○ Yes ○ No
22.18	Women of child baring age or male partners of women of child baring age and not practicing a method of acceptable birth control (d)	○ Yes ○ No

(a) Participants who are receiving stable chronic inhaled/nebulized antibiotics with no planned changes to treatment during the trial are eligible. Treatment with systemic macrolide or other oral prophylactic antibiotics are allowed, providing a stable dose, and initiation of treatment at least 3 months prior to screening and maintained throughout the trial.

(b) Participant receiving antipseudomonal antibiotics during the screening period may prolong the screening period to a maximum of 60 days and may be randomized provided they have a positive sputum sample for *P. aeruginosa* following cessation of antibiotic therapy. All eligibility criteria must be met prior to randomisation. Re- screening procedures to assess eligibility may be required.

(c) Asthma and COPD are common co-diagnoses in participants with bronchiectasis. Where a participant has a diagnosis of bronchiectasis plus either asthma or COPD, they may be enrolled in the trial if the clinician performing the screening assessment determines that bronchiectasis is the primary clinical diagnosis, i.e. where the participant's symptoms and exacerbations are primarily due to bronchiectasis in the opinion of the investigator.

(d) Women of childbearing potential must be willing to have pregnancy testing prior to trial entry and prior to each administration of trial medication dose.

22.19 Has a doctor on the Delegation Log confirmed all inclusion and exclusion criteria and documented this in the participant's medical notes? (If No - the doctor confirming inclusion and exclusion criteria must document this in the participant's medical notes prior to randomisation) ○ Yes ○ No

22.19.1 Date of Signing _____ _____ _____ (dd-mm-yyyy)

23. Concomitant Medications

Review each medication and check it is still ongoing at each visit

23.1 Review Concomitant Medications: Respiratory Medication

23.2 Review Concomitant Medications: Other Concomitant Medication

24. Adverse Events since last visit

Complete **Adverse Event Log** for each Adverse Event since last visit

25. Exacerbation recording

25.1 Has the participant experienced any symptoms of Exacerbation since last visit? ○ Yes ○ No

If Yes – complete Exacerbating Form

26. Vital Signs

Blood pressure – Systolic		mm Hg
Blood pressure – Diastolic		mm Hg
Pulse rate		beats/min
Temperature		°C
Oxygen saturation		%

27. Randomisation

27.1 Has the participant been randomised? ○ Yes ○ No

27.2 Date of Randomisation [ ] [ ] [ ] (dd-mm-yyyy)

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28. Blood Samples

28.1 Have pre-infusion research blood samples been obtained as per laboratory manual? ○ Yes ○ No

28.2 Have post-infusion research blood samples been obtained as per laboratory manual? ○ Yes ○ No

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29. Administration of Trial Medication

29.1 Was treatment given ○ Yes ○ No

29.1.1 **If No** – Reason not given

- ○ Previous reaction/toxicity (please ensure this has been recorded on the AE Log)
- ○ Other clinical decision
- ○ Participant's decision
- ○ Other

29.2.1 **If Other** – give reason

29.1.2 **If Yes** – Was trial medication given on date of visit? ○ Yes ○ No

29.1.2.1 **If 29.1.2 No** – Date Medication given [ ] [ ] [ ] dd/mm/yyyy

29.1.2.2 **If 29.1.2 No** –Reason trial medication not given on date of visit

- ○ Previous reaction/toxicity
- ○ Other clinical decision
- ○ Participant's decision
- ○ Other

29.3.1 **If Other** – please give reason

29.1.3 **If 29.1 is Yes** - Was IV antihistamine given prior to trial medication infusion? ○ Yes ○ No

29.1.3.1 **If No** –Reason not given
○ On regular oral antihistamine
○ Other

29.1.3.1.1 **If Other** –please give reason

29.1.4 **If 29.1.2 is Yes** - Was trial medication given as per protocol? (250ml over 240 minutes) ○ Yes ○ No

29.1.4.1 **If No** - Was infusion slowed or temporarily stopped? ○ Yes ○ No

29.1.4.1.1 **If Yes** - Reason infusion was slowed or temporarily stopped
○ Reaction/toxicity to trial infusion (Please ensure this has been recorded on AE Log)
○ Other clinical decision
○ Participant's decision
○ Other (an AE may need to be recorded)

29.4.1 **If Other** – please give reason

29.1.4.2 **If 29.1.4 No** - Was full volume (250mL) of infusion received? ○ Yes ○ No

29.1.4.2.1 **If No** - Total volume of infusion received? (NB Total volume of infusion should not be below 1 ml or be above 249 ml)

29.1.4.2.2 **If No** - Reason total volume of infusion not received
○ Reaction/toxicity to trial infusion (Please ensure this has been recorded on AE Log)
○ Other clinical decision
○ Participant's decision
○ Other (an AE may need to be recorded)

29.5.1 **If Other** – Please give reason

30. Questionnaires

30.1 Has the Quality of Life-Bronchiectasis Questionnaire (QOL-B) been completed? ○ Yes ○ No

30.2 Has the St George's Respiratory Questionnaire (SGRQ) been completed? ○ Yes ○ No

30.3 Has the Bronchiectasis Impact Measure Questionnaire (BIM) been completed? ○ Yes ○ No

31. Sputum samples

31.1 Have sputum samples for research been obtained as per laboratory manual? ○ Yes ○ No

31.2 Result of sputum colour assessment

- ○ Clear
- ○ Clear to yellow
- ○ Yellowish-green
- ○ Brownish-dark
- ○ Green with traces of blood
- ○ No sputum produced
- ○ Other

31.2.1 **If Other** – please provide details