Participant name:	
Hospital ID:	
CHI/Date of Birth:	

GREAT-2 GRemubamab ErAdication Trial

Sponsor	University of Dundee-NHS Tayside
Chief Investigator	Professor James Chalmers
IRAS number	1005993

Principal Investigator	
Contact number	
Contact email	

Visit 2 – Baseline & Randomisation, treatment dose 1
to be filed in medical notes as source data

Date of visit: | | Participant trial ID | | | | |

Please tick to indicate the following has been completed:

Confirmed participant's identity	
Participant has verbally given their consent to continue in the trial	
Participant was randomised as per protocol	
Concomitant medications have been reviewed	
Adverse events have been reviewed	
Exacerbations have been reviewed	

Research samples:

Blood samples pre-infusion	
Blood samples post-infusion	
Sputum	

Questionnaires:

Quality of Life-Bronchiectasis Questionnaire	
St George's Respiratory Questionnaire	
Bronchiectasis Impact Measure Questionnaire	

Vital signs pre-infusion, during infusion and post-infusion must be recorded and filed in the medical notes e.g. observation chart.

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Participant name:	
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Trial medication

Tick to confirm:

Participant was given pre-dose antihistamine prior to trial medication ☐
Name, dose and time of administration must be documented and filed in the medical notes e.g. prescription chart

Was trial medication given as per protocol? (250 ml over 240 minutes) ☐
Time of start of infusion must be documented and filed in the medical notes e.g. infusion chart
If not given as per protocol reason should be documented here

The following must be filed in the participant's medical notes:

- Eligibility criteria signed by doctor on the study delegation log
- Blood results from screening visit 1 signed and dated by doctor on delegation log
- Pregnancy test results, if applicable, signed & dated by doctor on delegation log
- Vital signs taken pre, during and post-trial medication administration
- Changes to concomitant medications since last visit
- Any adverse events since last visit
- Any pulmonary exacerbations since last visit
- Any other notable findings and actions taken
- Any paper copies of questionnaires
- If the participant was withdrawn from the trial at this visit, document reason

Any further information of note:

Visit has been carried out as per protocol

Signature:	
Name:	
Job title:	
Date:	

GREAT-2
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Participant name:	
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Participant trial ID				

To be completed by doctor delegated to confirm eligibility on the Delegation Log

Eligibility criteria check

Inclusion criteria:

1. Age 18-85	
2. Clinical diagnosis of Bronchiectasis	
3. Able to and provided informed consent	
4. Previous computerised tomography (CT) scan of the chest demonstrating bronchiectasis in 1 or more lobes	
5. A sputum sample that is culture or PCR positive for *P. aeruginosa* sent at the screening visit, within 35 days of randomization.	
6. P. aeruginosa in sputum, bronchoalveolar lavage or another airway sample at least once in the 24 months prior to screening.	

Exclusion criteria:

1. Known hypersensitivity to Gremubamab or any excipient of the investigational product	
2. Known clinical diagnosis of Cystic fibrosis	
3. Immunodeficiency requiring replacement immunoglobulin	
4. Active tuberculosis or nontuberculous mycobacterial infection (currently under treatment, or requiring treatment in the opinion of the investigator).	
5. Active allergic bronchopulmonary aspergillosis (receiving treatment with corticosteroids and/or antifungal medication)	
6. Recent significant haemoptysis (a volume requiring clinical intervention, within the previous 4 weeks prior to screening)	
7. Treatment with long term inhaled, systemic or nebulized anti-pseudomonal antibiotics which are newly initiated within the previous 3 months prior to screening	
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	
9. Receipt of antipseudomonal antibiotics for an exacerbation during the screening period	
10. Treatment with immunosuppressives within previous 6 months prior to screening	

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11. Participants with a primary diagnosis of Chronic obstructive pulmonary disease (COPD) associated with >10 pack years smoking history	
12. Participants with a primary diagnosis of asthma or asthma which is considered to be poorly controlled at screening	
13. Participants with FEV1 <25% predicted value at screening	
14. Use of any investigational drugs within five times of the elimination half-life after the last dose or within 30 days, whichever is longer	
15. 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	
16. Pregnant or lactating females	
17. Women of child baring age or male partners of women of child baring age and not practicing a method of acceptable birth control	

Eligibility sign off by delegated trial doctor:

Name _____

Signature _____

Date _____