GREAT-2 Worksheet – Visit 1 Screening

1. Informed Consent

1.1 Date of Screening V1 [ ] [ ] [ ] (dd-mm-yyyy)

1.2 Date of Informed Consent [ ] [ ] [ ] (dd-mm-yyyy)

1.4 Has the participant provided consent for blood and sputum samples to be stored for future research? ○ Yes ○ No

1.5 Has the participant provided consent for blood samples to be stored for future genetic research? ○ Yes ○ No

2. Demographics, Height & Weight

2.1 Age [ ]

2.2 Gender at birth ○ Male ○ Female

2.3 Ethnicity

○ English/Welsh/Scottish/Northern Irish/British
○ Irish
○ Gypsy or Irish Traveller
○ White and Black Caribbean
○ White and Asian
○ Indian
○ Bangladeshi
○ Any other Asian background
○ Caribbean
○ Any other Black/African/Caribbean background
○ Arab
○ Unknown
○ Any other White background
○ White and Black African
○ Any other Mixed/Multiple ethnic background
○ Pakistani
○ Chinese
○ African
○ Any other ethnic group

2.3.1 If Ethnicity is Any other ethnic group, then provide details [ ]

Height & Weight

2.4 Height
(to 2 decimal places)

m (to the nearest cm - e.g. 1.64m)

2.6 Weight
(to 1 decimal places)

kg (to the nearest 0.1kg e.g. 68.2kg)

3. Medical History

Has the participant had any of the following?
Please indicate any history of chronic medical conditions by selecting yes

3.1	Asthma	○ Yes	○ No
3.2	Nasal polyps	○ Yes	○ No
3.3	COPD	○ Yes	○ No
3.4	Rhinosinusitis	○ Yes	○ No
3.5	Angina	○ Yes	○ No
3.6	Atrial Fibrillation	○ Yes	○ No
3.7	Myocardial Infarction	○ Yes	○ No
3.8	Cardiac Failure	○ Yes	○ No
3.9	Liver Cirrhosis	○ Yes	○ No
3.10	Osteoporosis	○ Yes	○ No
3.11	Anxiety	○ Yes	○ No
3.12	Depression	○ Yes	○ No
3.13	Other relevant medical conditions	○ Yes	○ No

3.13.1 If yes, provide details

Has the participant had any of the following cancers?

3.14 Lung Cancer ○ Yes ○ No

3.14.1 If YES, currently active? ○ Yes ○ No

3.15 Haematological Malignancy ○ Yes ○ No

3.15.1 If YES, currently active? ○ Yes ○ No

3.16 Other Solid Tumours ○ Yes ○ No

3.16.1 If YES, currently active? ○ Yes ○ No

3.16.2 Details

4. Smoking History

4.1 What is the participant's smoking status?

○ Current

○ Ex

○ Never

4.2 Smoking Status Calculation

Pack years can be calculated at
https://www.smokingpackyears.com/

4.2.2 Approximate Pack Years

5. Concomitant Medications

Review participant medications and record on Concomitant Log.

5.1 Complete Concomitant Medications: Respiratory Medication

5.2 Complete Concomitant Medications: Other Concomitant Medication

Review the Concomitant Medications logs at each visit and ensure that Castor is updated.

6. Vital Signs

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

7. Spirometry

Bronchodilation given (as per WPG) ○ Yes ○ No

If **YES**

FEV1 Base (to 2 decimal places)		L
FVC Base (to 2 decimal places)		L
FEV1 % of predicted values (to 2 decimal places)		%
FVC % of predicted values (to 2 decimal places)		%
FEF 25-75% of predicted values (to 2 decimal places)		%

Participant ID [_] [_] [_] [_] Initials [_] [_] [_]

8. Bronchiectasis Severity Index

8.1 Has the participant been hospitalised with a severe exacerbation in the past 2 years? ○ Yes ○ No

8.2 Number of exacerbations in previous year ○ 0 ○ 1-2 ○ 3+

8.3 MRC Breathlessness Score

○ 1 - Not troubled by breathlessness except on strenuous exercise

○ 2 - Short of breath when hurrying or walking up a slight hill

○ 3- Walks slower then contemporaries on level ground because of breathlessness or has to stop for breath when walking at own pace

○ 4 - Stops due to breathlessness after walking 100m

○ 5 - Housebound due to breathlessness or breathless on dressing or undressing

8.4 Pseudomonas colonisation? Chronic colonisation is defined by the isolation of *P. aeruginosa* in sputum culture on 2 or more occasions, at least 3 months apart in a 1 year period. ○ Yes ○ No

8.5 Colonisation with other organisms? Chronic colonisation is defined by the isolation of potentially pathogenic bacteria in sputum culture on 2 or more occasions, at least 3 months apart in 1-year period. ○ Yes ○ No

8.6 Radiological severity

○ Less than 3 lobes involved
○ 3 or more lobes involved
○ Cystic bronchiectasis

Participant ID [_] [_] [_] [_] Initials [_] [_] [_]

9. ECG

9.1 Was ECG performed? ○ Yes ○ No

If **YES**

9.1.1 Date ECG was performed [ ] [ ] [ ] *(dd-mm-yyyy)*

9.1.2 If ECG was performed please specify result
- ○ Normal
- ○ Abnormal - not clinically significant
- ○ Abnormal - clinically significant

9.1.3 Was the ECG reviewed by a doctor prior to randomisation ○ Yes ○ No

9.1.3.1 Date of review [ ] [ ] [ ] *(dd-mm-yyyy)*

ECG must be reviewed prior to randomisation.

10. Physical Examination

10.1 Has Physical Examination been performed? ○ Yes ○ No
If no, Participant not eligible to take part in the trial

10.1.1 Respiratory
- ○ Normal
- ○ Abnormal - not clinically significant
- ○ Abnormal - clinically significant

10.1.1.1 If abnormal, provide details

Participant ID [_] [_] [_] [_] Initials [_] [_] [_]

10.1.2 Cardiovascular

- ○ Normal
- ○ Abnormal - not clinically significant
- ○ Abnormal - clinically significant

10.1.2.1 If abnormal, provide details

10.1.3 Abdominal

- ○ Normal
- ○ Abnormal - not clinically significant
- ○ Abnormal - clinically significant

10.1.3.1 If abnormal, provide details

10.1.4 Neurological

- ○ Normal
- ○ Abnormal - not clinically significant
- ○ Abnormal - clinically significant

10.1.4.1 If abnormal, provide details

Participant ID [_] [_] [_] [_] Initials [_] [_] [_]

10.1.5 Dermatological
- ○ Normal
- ○ Abnormal - not clinically significant
- ○ Abnormal - clinically significant

10.1.5.1 If abnormal, provide details

10.1.6 Other
- ○ Abnormal - not clinically significant
- ○ Abnormal - clinically significant

10.2.1 If 'Other' is 'Abnormal' provide details

Participant ID [_] [_] [_] [_] Initials [_] [_] [_]

11. Inclusion Criteria

11.1	Age 18-85	○ Yes ○ No
11.2	Clinical diagnosis of Bronchiectasis	○ Yes ○ No
11.3	Able to and provided informed consent	○ Yes ○ No
11.4	Previous computerised tomography (CT) scan of the chest demonstrating bronchiectasis in 1 or more lobes	○ Yes ○ No
11,5	*P. aeruginosa* in sputum, bronchoalveolar lavage or another airway sample at least once in the 24 months prior to screening*	○ 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 will be deemed met and the participant may be enrolled.

Participant ID [_] [_] [_] [_] Initials [_] [_] [_]

12. Exclusion Criteria

12.1	Known hypersensitivity to Gremubamab or any excipient of the investigational product	○ Yes ○ No
12.2	Known clinical diagnosis of Cystic fibrosis	○ Yes ○ No
12.3	Immunodeficiency requiring replacement immunoglobulin	○ Yes ○ No
12.4	Active tuberculosis or nontuberculous mycobacterial infection (currently undertreatment, or requiring treatment in the opinion of the investigator).	○ Yes ○ No
12.5	Active allergic bronchopulmonary aspergillosis (receiving treatment with corticosteroids and/or antifungal medication)	○ Yes ○ No
12.6	Recent significant haemoptysis (a volume requiring clinical intervention, within the previous 4 weeks prior to screening)	○ Yes ○ No
12.7	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
12.8	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
12.9	Receipt of antipseudomonal antibiotics for an exacerbation during the screening period (b)	○ Yes ○ No
12.10	Treatment with immunosuppressives within previous 6 months prior to screening	○ Yes ○ No
12.11	Participants with a primary diagnosis of Chronic obstructive pulmonary disease (COPD) associated with >10 pack years smoking history (c)	○ Yes ○ No
12.12	Participants with a primary diagnosis of asthma or asthma which is considered to be poorly controlled at screening (c)	○ Yes ○ No
12.13	Participants with FEV1 <25% predicted value at screening	○ Yes ○ No

Participant ID [_] [_] [_] [_] Initials [_] [_] [_]

12.14	Use of any investigational drugs within five times of the elimination half-life after the last dose or within 30 days, whichever is longer	○ Yes ○ No
12.15	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	○ Yes ○ No
12.16	Pregnant or lactating females	○ Yes ○ No
12.17	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.

13. Pregnancy Test - Serum

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

13.1 Has blood been taken for serum pregnancy test? ○ Yes ○ No ○ NA

14. Blood Samples

Form Full Blood Count

14.1 Have NHS samples been obtained? ○ Yes ○ No
NHS blood samples are mandatory

14.1.1 If **YES**

Date of sample [ ] [ ] [ ] (dd-mm-yyyy)

Haemoglobin unit ○ g/L ○ g/dL

Haemoglobin [ ]

White cell count [ ] x10^9/L

Neutrophil count [ ] x10^9/L

Eosinophil count [ ] x10^9/L

Platelets [ ] x10^9/L

Click NEXT to go to UEC

Form Urea and Electrolytes, Creatinine (UEC)

Sodium mmol/L [ ]

Potassium [ ] mmol/L

Creatinine [ ] mmol/L

Urea [ ] mmol/L

eGFR [ ] ml/min

Click NEXT to go to LFT

Form Liver Function Test (LFT)

Albumin		g/L
Bilirubin		umol/L
Alkaline Phosphatase		U/L
Alanine Aminotransferase		U/L

14.2 Have research blood samples been obtained as per laboratory manual? ○ Yes ○ No

15. Sputum sample for *P. aeruginosa* testing

15.1 Has Sputum sample for *P. aeruginosa* testing been collected? ○ Yes ○ No