

**Supplementary Table 2. Criteria for discontinuation of the trial treatment**

We discontinue the trial treatment if any of the following defined criteria are met:

- If the objective disease progression is observed
- If the patient requests to withdraw from the study treatment.
- If it is difficult to continue the administration of the investigational drug due to worsening comorbidities.
- When it is difficult to continue the administration of the investigational drug due to adverse events.
- If a subject becomes pregnant.
- In any other cases where, at the discretion of the investigator or co-investigator, it is deemed necessary to discontinue the administration of the investigational drug.