

Appendix E.

Table S3. Individual Patient Listings and Details for Treatment-Related SAEs and AEs of Active Tuberculosis Cases for PLANETRA study

	CT-P13 3 mg/ kg		
Patient No.	0306-3026*	1208-3002	2201-3005
Age/Sex/ Race ¹	27/F/A	58/F/W	37/F/O: Hispanic
Geographical area	Non-European region - Philippines	European region – Eastern Europe (Poland)	Non-European region - Latin America (Mexico)
Indication	Rheumatoid arthritis	Rheumatoid Arthritis	Rheumatoid arthritis
Interferon-gamma release assay	Screening – Negative Week 14 – Positive End-of-Study – Positive	Screening - Negative	Screening – Negative Unscheduled - Positive
Condition / Diagnosis	Pulmonary TB	Miliary TB (Disseminated TB)	Disseminated TB ²
Severity	Moderate	Moderate	Severe
Related / Unrelated to Drug	Definite	Probable	Definite
BCG vaccination	Yes	Yes	Yes
Treatment	Anti-TB drugs	Anti-TB drugs	Anti-TB drugs
Outcome to Treatment	Recovered/Resolved	Recovered/Resolved	Recovering/Resolving
Action	Permanently discontinued	Permanently discontinued	Permanently discontinued
Medical history	Osteonecrosis	Cholelithiasis Cholecystectomy	Sjogren's syndrome Ulcerative keratitis
Immunosuppressants used	METHOTREXATE(JAN2007)	METHOTREXATE(22JUN2010) METHYLPREDNISOLONE(05MAY2009~)	METHOTREXATE(03MAY2007) PREDNISONE(03MAY2007~)

¹ F = Female, W = White, A = Asian, O = Other

² Disseminated TB was reported as a TEAE for this patient as a recovering/resolving condition of the SAE

* Unconfirmed TB diagnosis defined as clinical symptoms compatible with TB in the absence of an alternative diagnosis without evidence of M. tuberculosis culture growth, molecular diagnostics or histopathological examination

Two of the cases were considered moderate and one severe in severity. As these numbers are generally low these events are likely chance findings. All of these cases came from regions or countries with an increased prevalence and incidence of TB: Estimated rates in the Philippines of 275, Mexico 16, Latvia 39, Republic of Korea 97 and Poland of 23 per 100,000 population compared to Western Europe countries: e.g. France 9.3, and Germany 4.8 per 100,000 population (WHO TB cases by region, 2010, WHO TB cases by country, 2010).