

TSFAE01: Overall Summary of Treatment-emergent Adverse Events; All Treated Analysis Set (Study 64407564MMY1001)

	SC				IV	Total
	RP2D (400 ug/kg weekly)	RP2D (800 ug/kg Bi-weekly)	Non-RP2D (<RP2D)	Non-RP2D (>RP2D)	Prior T cell exposures at RP2Ds	
Analysis set: All Treated						
Any TEAE						
Study drug-related ^a						
Maximum toxicity grade						
Grade 1						
Grade 2						
Grade 3						
Grade 4						
Grade 5						
Any serious TEAE						
Study drug-related ^a						
TEAE leading to discontinuation of study drug ^b						
TEAE with outcome death ^c						
Death due to COVID-19						
COVID-19 TEAEs						
COVID-19 serious TEAEs						

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Key: TEAE = treatment-emergent adverse event; IV = intravenous, SC = subcutaneous, RP2D=recommended Phase 2 dose; CRS=cytokine release syndrome; ICANS=immune effector cell-associated neurotoxicity.

Note: IV includes all IV treatment groups; Non-RP2D(<RP2D) includes 5 ug/kg weekly, 15 ug/kg weekly, 45 ug/kg weekly and 135 ug/kg weekly treatment groups; Non-RP2D(>RP2D) includes 800 ug/kg weekly, 1200 ug/kg bi-weekly and 1600 ug/kg monthly treatment groups; Prior T cell exposures at RP2Ds includes Phase 1 RP2D 400 ug/kg weekly with prior CART or prior bispecific, Phase 1 RP2D 800 ug/kg biweekly with prior CART or prior bispecific and Phase 2 Cohort B treatment groups.

Note: The output includes the diagnosis of CRS and ICANS; the symptoms of CRS or ICANS are excluded.

Note: Adverse events are reported until 100 days (Phase 1) or 30 days (Phase 2) after the last dose of Talquetamab or until the start of subsequent anticancer therapy, if earlier.

Note: Percentages calculated with the number of subjects in the all treated analysis set as denominator.

Note: Adverse events are graded according to the NCI-CTCAE Version 4.03, with the exception of ICANS and CRS. CRS was originally graded by Lee criteria (Lee et al 2014) in Phase 1 and by ASTCT consensus grading system (Lee et al 2019) in Phase 2, with conversion of grade in Phase 1 RP2D to ASTCT based on data in eCRF.

Toxicity grade for CRS by ASTCT is presented in this table, for both Phase 1 RP2D and Phase 2. For IV and SC Non-RP2D CRS toxicity grading is presented based on Lee criteria. Toxicity grade for ICANS by ASTCT is also presented in this table.

^a TEAEs related to study drug

^b Includes those subjects indicated as having discontinued treatment due to an adverse event on the end of treatment CRF page.

^c TEAE with outcome death on the AE eCRF page.

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