

Table 8-1 Non-serious and serious adverse event reporting

<p>From Enrollment through Month 60 post infusion / Re-baseline# to RI# Month 60 post infusion</p>	<p>> Month 60 through Year 15 post infusion / >RI# Month 60 through RI# year 15 post infusion</p>
<p>Any non-serious AEs \geq Grade 3 and any SAEs irrespective of Grade with at least a possible causal relationship to CAR-T product *</p>	<p>Any SAEs with at least a possible causal relationship to CAR-T product*</p>
<p>The following AEs (i.e., non-serious AE and SAEs, if not otherwise specified) should be reported to Novartis regardless of causality:</p> <ul style="list-style-type: none"> • AEs with fatal outcome • Serious neurologic disorder • Progressive multifocal leucoencephalopathy (PML) • Serious prolonged depletion of normal B cells/ agammaglobulinemia • New occurrence or exacerbation of an autoimmune disorder • Serious hematological disorders (incl. aplastic anemia and bone marrow failure) • Positive RCL test result • New secondary T-cell or non T-cell malignancy other than the primary underlying malignancy • Vector insertion site sequencing result with a mono-or oligoclonality pattern or in a location near a known human oncogene 	