FORM TITLE: **Dose Limiting Toxicity**

Instructions: *Complete this form if any dose limiting toxicities (DLT) occur during the trial's safety monitoring period (from the day of the 1st AdV-tk injection until completion of the last prodrug). Also, complete an AE Form for the event and attach it to this form.*

Protocol Case #: _____ Date of the event: ___/___/____

Patient Name: _____ or Initials and DOB: ____ ___/___/____

DLT occurred after: ☐ 1st injection ☐ 2nd injection ☐ 3rd injection

Dose Limiting Toxicity:

☐ Any unexpected and possibly related* grade 4 toxicity

☐ Any unexpected possibly related* grade 3 toxicity that delays standard treatment by more than 2 weeks

**Possibly related refers to the AdV-tk + valacyclovir experimental intervention*

See protocol section 6.2 for Stopping Rules

Section 1: DLT Report (Designation to be made by clinical investigator)

Primary Event_____ *CTCAE ver* 4.0 *Grade*_____

Start Date: _____ End Date: _____ If ongoing, check box ☐

Description and/or attach separate documents explaining the reasons why this event is being reported as a DLT (If AE form has not previously been submitted for this event, please complete form and attach.)

Documents Attached:

☐ Detailed Description of DLT ☐ H&P ☐ Labs

☐ Imaging ☐ Other:

Section 2: Follow up Action

Date of Follow Up: _____/_____/_____

Follow up Action Taken:

After final review, was this event determined to be a DLT? ☐ Yes ☐ No

Explanation:

_____

Investigator name and signature