SUPPLEMENT 1. Pharmacokinetic Measurements

Serum samples for bezlotoxumab concentrations were collected on Day 1, Day 10, and at Weeks 4, 8, and 12 and were analyzed by PPD, Inc. (Richmond, Virginia, USA) in an unblinded manner. The validated analytical method used was an ECL assay. The LLOQ for bezlotoxumab in human serum was 100 ng/mL to 6400 ng/mL in 100% human serum and the analytical range was 10.0 ng/mL to 640 ng/mL using a 1:10 minimum dilution.

Bezlotoxumab serum concentrations and actual blood sampling times relative to the time of dose were used to determine PK parameters for each participant. All values below the limit of quantification were replaced by zero. PK parameters were calculated using software PhoenixTM 64 (Version 8.4.3). C_{max} and T_{max} were generated by WinNonlin from each participant's concentration-time data. The first-order rate constant associated with the terminal (log-linear) portion of the curve (λz) was estimated by linear regression of the time versus log-concentration profile. The terminal half-life ($t_{1/2}$) was calculated as the quotient of the natural log of 2 (ln[2]) and λz. All AUC parameters were calculated using the linear trapezoidal method for ascending concentrations and the log trapezoidal method for descending concentration (linear-up/log-down). Clearance (CL) was calculated as Dose/$AUC_{0\text{-}inf}$ and the volume of distribution (V_d) was calculated as Dose/($AUC_{0\text{-}inf}$* λz). For apparent terminal $t_{1/2}$, V_d and CL, the percent CV was calculated in the natural log-scale with the equation: 100 x sqrt(exp(s^2) - 1), where s^2 is the observed variance on the natural log-scale.