CUDC-907-301 is a Phase 1/2, open-label, dose-escalation study of fimepinostat (CUDC-907) in combination with venetoclax in patients with R/R DLBCL or HGBL with or without MYC and BCL2 alterations.

The primary objectives are to determine MTD, RP2D, safety, tolerability, and to assess preliminary efficacy, as measured by ORR and DOR. Approximately 15 pts in the Phase 1 dose escalation (3+3 design) and 30 pts in the Phase 2 expansion will be enrolled to receive fimepinostat + venetoclax treatment. Patients will be treated until progression or unacceptable toxicity. The Ph 2 expansion will be an estimation study for detecting an efficacious signal. Patients who receive 21 dose and have 21 post-baseline response evaluation will be included in the efficacy analysis set. Investigator-assessed ORR based on Lugano criteria will be summarised as the proportion of pts who achieve a best response of CR/PRI and the corresponding two-sided 95% confidence interval (CI). The median DOOR will be summarised for pts who achieve response using Kaplan-Meier (KM) product-limit method. The median DOOR along with the two-sided 95% CI using the Brookmeyer and Crowley method will be calculated. PFS and OS will be estimated in pts using the KM product-limit method, along with 95% confidence intervals.

The first patient in this study was treated in August 2019, and enrollment is ongoing. This new study represents the first clinical trial of the novel combination of fimepinostat with venetoclax in pts with DLBCL or HGBL harboring alterations of both MYC and BCL2. Clinical trial: NCT01742988.