GRN1005 PHASE I STUDIES
FINAL RESULTS

Introduction

- GRN1005 (formerly ANG1005-02) is a <br> pegylated drug conjugate (PDC) that is being evaluated for the potential treatment of relapsed and refractory solid tumors.
- P-gp, the ATP-binding cassette subfamily B member 1 (ABCB1) encoded transport protein, which is overexpressed in a variety of tumor types, including metastatic brain tumors. GRN1005 is not a substrate for the P-gp efflux transporter and is therefore not effluxed out of the cell.

Design

- Paclitaxel has proven efficacy against various tumors; however, its use to treat brain tumors has been hampered by its inability to cross the BBB and to reach the tumor cells at therapeutic levels [6,7].
- Targeted treatment of metastatic and primary brain cancers
- Prospectively collect tumor samples from patients scheduled for debulking surgery 4-6 hours after the last dose of drug administration.

GRN1005 Metastatic Brain Tumor Sub-Study

- Malignant glioma (WHO Grades II to IV)
- Patients Adult patients with progressing metastases; ECOG PS ≤ 2
- Oral candidiasis 0 0 2 (11.1%)
- Neuropathy peripheral 5 2 (11.1%) 0 5 (27.8%)

Pharmacokinetics

- Overall incidence of infusion reactions of any grade was [23%] Grade 3, and 1/38 [3%] Grade 4)
- The overall incidence of infusion reactions of any grade

Methods

- Table 1. Number of Patients in Each Dose Cohort (420 mg/m2 or above) in Each Study
- Table 2. Number of Patients in Each Dose Cohort (420 mg/m2 or above) in Each Study

Safety

- Table 3. Number of Patients in Each Cohort (420 mg/m2 or above) in Each Study
- Table 4. Summary of Grade ≥ 3 Infusion Reactions by Cohort

Tumor Response in 2-D: ANG1005-CLN-01

- Table 5. Summary of Best Overall Response Assessment (1-D) by Brain Tumor Subtype and Grade
- Table 6. Summary of Best Overall Response Assessment (1-D) by Brain Tumor Subtype and Grade

Conclusions

- Given the clinical activity and safety/tolerability observed in Phase I, GRN1005 as a single-agent therapy is being further investigated in Phase 2 studies.

References