gossamerbio

3013 Science Park Road, Suite 200
San Diego, CA 92121

O 858-684-1300
F 858-625-0146

Protocol GB5121-2101
EudraCT: 2021-006234-39

Full Title of the Trial

A Phase 1b/2, open-label dose escalation with expansion study of GB5121 in adult patients with relapsed/refractory primary or secondary central nervous system lymphoma or primary vitreoretinal lymphoma, with a Phase 2 open-label single dose level study of GB5121 in adult patients with relapsed/refractory primary central nervous system lymphoma

SUMMARY OF RESULTS

This phase 1b/2 study of GB5121 in patients with relapsed/refractory (r/r) central nervous system lymphoma (CNSL) or primary vitreoretinal lymphoma (PVRL) was terminated prematurely by the Sponsor while the Phase 1b Dose Escalation phase of the study was ongoing due to the observed benefit/risk profile and for business considerations. The planned Phase 1b Dose Expansion and the Phase 2 parts of the study were not initiated.

A total of 12 patients were treated and included in the Safety Population, with 6 patients treated at the 10 mg BID dose level and 3 patients treated at each of the 20 mg and 30 mg BID dose levels.

An elderly, very ill population with generally poor prognosis and limited treatment options was enrolled. The Safety Population was 50.0% female with a mean (SD) age of 73.2 (6.70) years and 50.0% of patients age 75 or older. Mean (SD) time since initial diagnosis was 2.25 (2.438) years. The most common cancer type at study entry was primary CNSL (PCNSL) (58.3%, 7 of 12 patients), followed by secondary CNSL (SCNSL) (33.3%, 4 of 12 patients) and PVRL (8.3%, 1 of 12 patients). Most patients (75.0%, 9 of 12 patients) presented with relapse of disease as compared to refractory disease (25.0%, 3 of 12 patients), and most patients (91.7%, 11 of 12 patients) had received prior systemic cancer treatment.

The primary endpoints of the overall incidences of adverse events (AEs), dose-limiting toxicity (DLTs), and serious AEs (SAEs) were 100.0% (12 of 12 patients in Safety Population), 8.3% (1 of 12 patients in DLT Evaluable Population who had a CTCAE Grade 5 cerebral haemorrhage), and 41.7% (5 of 12 patients in Safety Population), respectively.
Given the premature termination of the study while Phase 1b Dose Expansion was ongoing, the optimal biological dose (OBD) and/or maximum tolerated dose (MTD) and recommended Phase 2 dose (RP2D) of GB5121 were not determined.

Individual AE PTs with an overall incidence of more than 1 patient were asthenia (25.0%, 3 of 12 patients), and atrial fibrillation, COVID-19, diarrhoea, fall, fatigue, and myalgia (16.7%, 2 of 12 patients each).

The incidence of AEs of CTCAE Grade 3 or higher was 58.3% (7 of 12 patients). The incidence of AEs related to GB5121 was 75.0% (9 of 12 patients), and the incidence of SAEs related to GB5121 was 16.7% (2 of 12 patients). The incidence of AEs leading to discontinuation of GB5121 was 33.3% (4 of 12 patients).

A total of 4 of 12 patients (33.3%) died, including 3 of 12 (25.0%) patients with an AE resulting in death and 1 patient who died due to disease progression. The 3 patients who died due to AEs had fatal AEs of cerebral haemorrhage (assessed as not related to GB5121 by the Investigator, but related to GB5121 by the Sponsor), sudden death (assessed as related to GB5121), and fall (assessed as not related to GB5121).

CONCLUSION

This study of GB5121 in r/r CNSL or PVRL patients enrolled an elderly, very ill population with generally poor prognosis and limited treatment options. The study was terminated prematurely, while Phase 1b Dose Escalation was ongoing, due to the observed benefit/risk profile and for business considerations. Therefore, the OBD and/or MTD and RP2D of GB5121 were not determined, and Phase 1b Dose Expansion and Phase 2 were not initiated.