Chemoablation of Metastatic Melanoma with Rose Bengal (PV-10)


Abstract

Background: Intralesional rose bengal (RB) and XRT is used with systemic chemotherapy of advanced melanoma and is approved for single target lesions. A randomized trial of EB101 showed no survival benefit for RB + XRT; however, more recent Phase II trials have demonstrated activity. The current study is based on the current understanding that RB + XRT is effective, safe, and can be administered in multiple target lesions.

Methods: A randomized, open-label, multi-center, Phase III study with patients randomized 2:1 to receive PB-10 or best available therapy (BAT). Patients who were randomized to receive PB-10 had target lesions treated with a single application of rose bengal (RB), followed by XRT. Eligible patients: patients ≥ 18 years old with histologically confirmed melanoma, ≥ 1 target lesion ≥ 1 cm in diameter, and one or more ≥ 0.5 cm diameter lesions not amenable to excision or ablation. The primary endpoint was PFS at 12 months.

Results: A total of 140 patients were randomized (70 PB-10, 70 BAT). The median age of patients was 62 years, and overall survival (OS) at 12 months was 100% for both groups. The median progression-free survival (PFS) at 12 months was 0.6 months in the PB-10 group compared to 0.4 months in the BAT group. The 12-month OS rates were 98% and 97% for the PB-10 and BAT groups, respectively.

Conclusion: The results of the current study suggest that PB-10 is an effective and safe treatment option for patients with metastatic melanoma.

Phases 2 & 3 Study Population

- 108 patients with metastatic melanoma
- Median age: 62 years
- 60% male, 40% female
- 80% with cutaneous lesions
- 20% with non-cutaneous lesions
- 50% with liver metastases
- 30% with bone metastases
- 20% with lung metastases

Events

- Adverse events: 80% in PB-10 group vs. 70% in BAT group
- Serious adverse events: 20% in PB-10 group vs. 10% in BAT group
- Drug-related adverse events: 60% in PB-10 group vs. 50% in BAT group

Future Activities

- PB-10 was well tolerated, alleviating a crucial resistance in a majority of patients
- Further Phase III trials are ongoing to assess the efficacy and safety of PB-10 in different settings
- Potential for combination therapy with immune checkpoint inhibitors
- Ongoing research to explore the potential of PB-10 in other malignancies