INTRODUCTION

The safety and efficacy of relacorilant, a selective GR modulator, were evaluated in a Phase 1 study in patients with advanced cancer. Relacorilant was dosed as intermittent treatments at 150 mg/80 mg/m², with a Phase 2 dose of 100 mg/day for advanced solid tumors. The most common Grade ≥3 adverse events were neutropenia, abdominal pain, and leukopenia. The recommended Phase 2 dose for the advanced solid tumor cohorts was relacorilant at 100 mg/day.

METHODS

STUDY DESIGN

The Phase 1 and Phase 2 studies were open-label, single-arm, dose-escalation studies. Patients with advanced solid tumors were eligible for the Phase 1 study. Patients with advanced solid tumors were eligible for the Phase 2 study. Safety assessments were performed in all patients who had received at least a single dose of relacorilant. The response-evaluable populations included patients with advanced solid tumors who had received at least a single dose of relacorilant.

RESULTS

BASELINE CHARACTERISTICS AND DEMOGRAPHICS

In the intent-to-treat population, all patients received at least a single dose of relacorilant (Table 1). A pre-specified analysis of Grade ≥3 adverse events was performed in all patients who had received at least a single dose of relacorilant. The response-evaluable populations included patients with advanced solid tumors who had received at least a single dose of relacorilant.

SAFETY AND DETERMINATION OF RP2D

Glucocorticoid (100 nM dexamethasone) reduced the half-maximal potency of paclitaxel, oxaliplatin, and gemcitabine in the MIA PaCa-2 xenograft model (Fig 2). This effect was dose dependent with maximal reduction of ∼70% at 1 μM dexamethasone. This dose of dexamethasone was chosen for the study.

EPIGEOGRAPHY

The safety and efficacy of relacorilant were evaluated in patients with advanced solid tumors. Relacorilant was dosed as intermittent treatments at 150 mg/80 mg/m², with a Phase 2 dose of 100 mg/day for advanced solid tumors. The most common Grade ≥3 adverse events were neutropenia, abdominal pain, and leukopenia. The recommended Phase 2 dose for the advanced solid tumor cohorts was relacorilant at 100 mg/day. The response-evaluable populations included patients with advanced solid tumors who had received at least a single dose of relacorilant.

CONCLUSIONS

Relacorilant was well tolerated in patients with advanced solid tumors. The safety and efficacy of relacorilant were evaluated in patients with advanced solid tumors. Relacorilant was dosed as intermittent treatments at 150 mg/80 mg/m², with a Phase 2 dose of 100 mg/day for advanced solid tumors. The most common Grade ≥3 adverse events were neutropenia, abdominal pain, and leukopenia. The recommended Phase 2 dose for the advanced solid tumor cohorts was relacorilant at 100 mg/day. The response-evaluable populations included patients with advanced solid tumors who had received at least a single dose of relacorilant.

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3. Clinicaltrials.gov: NCT02762981

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