Efficacy and safety of entinostat (ENT) and pembrolizumab (PEMBO) in patients with non-small cell lung cancer (NSCLC) previously treated with anti-PD-(L)1 therapy.


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METHODS
Key Patient Eligibility Criteria
- Histologically- or cytologically-confirmed adenocarcinoma or squamous cell carcinoma
- Previous systemic therapy limited to 1 prior chemotherapy regimen
- 18-70 years old
- ECOG performance status of 0-1
- Adequate organ function
- Not pregnant or breastfeeding
- At least 14 days since last dose of prior PD-(L)1 therapy
- No evidence of brain metastases
- No prior anti-angiogenic therapy
- Not eligible for enrolling in any other investigational or approved therapy
- At least 2 years from prior anti-angiogenic therapy
- At least 1 month from prior anti-hormone therapy

Study Design
The Phase 2 expansion phase of SWOG S0802, a Simon 3+3 design to determine the number of patients at each dose level. The initial cohort was based on a single proportion testional test with 90% power and a 0.05 significance level. The maximum number of patients enrolled in each cohort was 10 (3/3/4/5 in 5 mg QW PO + pembrolizumab 200 mg Q3W IV). The study was withdrawn due to fewer than 3 patients in 70 patients to secure 4 additional doses to determine dose-toxicity.

The primary population was enrolled on 90% as per IBCST criteria.