

T-7

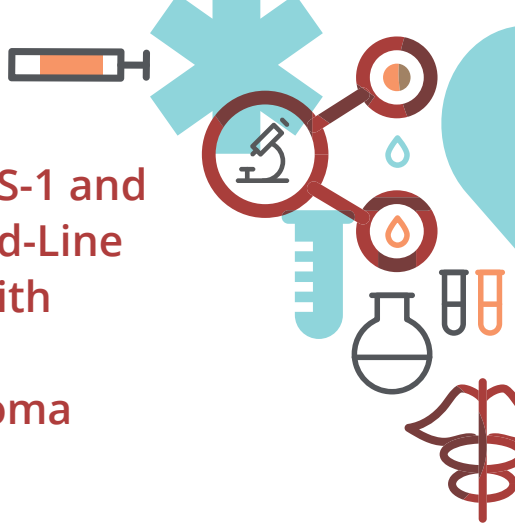
A Pilot Phase 2 Study of S-1 and Temozolomide as Second-Line Treatment in Patients with Advanced or Metastatic Neuroendocrine Carcinoma

Xin Wang¹; Zhirong Qi²; Huangying Tan²

¹Beijing University of Chinese Medicine; ²China-Japan Friendship Hospital

BACKGROUND: Neuroendocrine carcinoma (NEC) is a group of highly malignant and invasive rare tumors with few treatment options. Due to its malignancies, many patients missed the opportunity of surgery at the time of diagnosis. For the patients with advanced or metastatic NEC, platinum-based chemotherapy is often used as first-line treatment. There is no standard second-line treatment for patients with disease progression or intolerance to platinum-based first-line treatment. According to our clinical observation, some patients with NEC are effectively treated with S-1 combined with temozolomide regimen. The goal of this phase 2 pilot study is to evaluate the utility of S-1 and temozolomide treatment in NEC.

METHODS: This study is a prospective, single arm, single institution pilot phase 2 study to evaluate the efficacy and safety of S-1(40-60mg orally twice daily, days 1-14)and temozolomide(200mg orally once daily, days 10-14) every 21 days as second-line treatment in patients with advanced or metastatic NEC. Patients will be treated until disease progression. Tumor response will be assessed by CT/MRI at baseline then every 6 weeks until progression or intolerance of the toxicity. The primary endpoint is overall response rate (ORR) measured by RECIST 1.1. This study will enroll 40 patients with ECOG performance status of 0-2. The key eligibility criteria is measurable unresectable or metastatic disease of NEC. Patients must have progressed or have been intolerant to platinum-based chemotherapy.



RESULTS: This study is now active and open for enrollment. The anticipated enrollment period is 12 months.

CONCLUSION: This pilot phase 2 study may show evidence of promising safety and efficacy of S-1 and temozolomide in NEC patients who progressed on or failed platinum-based chemotherapy.