Pancreatic cancer remains a clinically challenging disease with an 80% mortality rate within 12 months of initial diagnosis (ACS Estimates). Recent clinical trials have shown median survival of up to four to six months with single agent RECIST response rates in the second- line setting (Connolly et al. 2011; NAPOLI-1). The standard of care remains toxic chemotherapy regimens (FOLFIRINOX or gemcitabine with nab-paclitaxel) with grade 3 or greater toxicity in over 50%.

Currently, there are no FDA approved treatments specifically indicated for front-line metastatic pancreatic adenocarcinoma. Neither ASCO nor NCCN guidelines recommend any treatment for third-line pancreatic cancer patients. SM-88 is a novel anti-cancer agent that consists of one investigational agent (DL-alpha-methyltyrosine, D,L), and three repurposed drugs (metyrosine, phenytoin, and androstan). It is hypothesized that all four, including both the D/L isomers contribute to the anti-tumor activity of SM-88 in Patients with Metastatic Pancreatic Cancer: A Phase II Trial of SM-88 Monotherapy in the Fourth Line Setting. The present study describes the efficacy results from randomized Part 1 of Tyme Technologies, Inc., NY, NY; Tyme Technologies, Inc., ry.

In Part 1, subjects were randomized to receive one of two D,L alpha-methyltyrosine oral monotherapy dosing regimens, 230 mg BD, or 460 mg BD. The trial of metyrosine (10 mg OD), phenytoin (50 mg OD), and androstan (0.5 mg OD), were the same regardless of randomization. The present study describes the efficacy results from randomized Part 1 of Tyme-88-Phac (NCT01351295) is a 2 Part randomized, open-label Phase II trial of SM-88 in 111 pretreated patients with metastatic pancreatic adenocarcinoma with at least 1 prior line of chemotherapy, and an Eastern Cooperative Oncology Group (ECOG) score ≤ 2. Progression metastatic pancreatic adenocarcinoma with at least 1 prior line of chemotherapy, and an Eastern Cooperative Oncology Group (ECOG) score ≤ 2. It is hypothesized that all four, including both the D/L isomers contribute to the anti-tumor activity of SM-88 in Patients with Metastatic Pancreatic Cancer: A Phase II Trial of SM-88 Monotherapy in the Fourth Line Setting. The present study describes the efficacy results from randomized Part 1 of Tyme Technologies, Inc., NY, NY; Tyme Technologies, Inc., ry.

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