SM-88 THERAPY IN HIGH-RISK POOR PROGNOSIS PanCREATIC CANCER

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INTRODUCTION

- TYME conducted a multi-center*, open-label, dose optimization randomized Phase II trial evaluating SM-88 in advanced Pancreatic Ductal Adenocarcinoma (PDAC).
- SM-88 is the lead investigational therapy in the TYME Cancer Metabolism Based Therapies (CMBTSM)™ platform. SM-88 is an oral modified dysfucntional tyrosine that is hypothesized to disrupt cancer cell metabolism.
- SM-88 has demonstrated encouraging efficacy and a well-tolerated safety profile in 15 different tumor types, including solid tumors and hematologic malignancies across four separate studies.

METHODS

- Phase II trial of PDAC with radiographic PD, after at least 1 prior line and ECOG PS ≤2. Patients randomized to 460 or 520 mg/d of SM-88; all received methotrexal 10 mg, phenytoin 50 mg and sirolimus 0.5 mg per day.
- 99 patients were consented for screening and 49 met criteria for randomization.
- 10 patients did not complete at least one cycle of SM-88 treatment (median 17 days; range 7 – 26 total time on treatment) and were considered not evaluable for efficacy as per protocol. One patient had unreported survival data.

RESULTS

- Of the 49 patients randomized, 40 (81.6%) were evaluable for safety and efficacy. No patients withdrew due to AEs.
- Of the 365 AEs reported, 63% were grades ≤1.
- The most common AEs in the evaluable group were rash (abdominal pain, arthralgia, and hypotension) with 12% of patients reported experiencing these AEs.
- Prior lines of therapy and ECOG PS ≥2 were not prognostic for survival.

CONCLUSIONS

- TYME conducted a multi-center*, open-label, dose optimization randomized Phase II trial evaluating SM-88 in advanced Pancreatic Ductal Adenocarcinoma (PDAC).
- SM-88 is the lead investigational therapy in the TYME Cancer Metabolism Based Therapies (CMBTSM)™ platform. SM-88 is an oral modified dysfucntional tyrosine that is hypothesized to disrupt cancer cell metabolism.
- SM-88 has demonstrated encouraging efficacy and a well-tolerated safety profile in 15 different tumor types, including solid tumors and hematologic malignancies across four separate studies.

REFERENCES

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