AB040. P-08. FOENIX-CCA2: a phase 2 study of TAS-120 in patients with intrahepatic cholangiocarcinoma harboring FGFR2 gene rearrangements

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Abstract: TAS-120 is a highly selective, irreversible fibroblast growth factor receptor (FGFR) 1–4 inhibitor in development as a once-daily oral treatment for intrahepatic cholangiocarcinoma (iCCA). An ongoing phase 1/2 study of TAS-120 in CCA showed tolerability and preliminary efficacy, particularly in patients with FGFR2 rearrangements. The purpose of FOENIX-CCA2 (NCT02052778) is to evaluate the efficacy and safety of TAS-120 in patients with iCCA with FGFR2 gene rearrangements. FOENIX-CCA2 is a global, single-arm study of TAS-120 in patients with iCCA bearing FGFR2 gene fusions and other rearrangements including deletion, duplication, truncation, or rearrangement of unknown significance. The study will enroll approximately 100 patients with locally advanced or metastatic iCCA that progressed after ≥1 systemic therapies and with an ECOG PS of 0 or 1. Prior systemic therapy must include gemcitabine plus platinum-based chemotherapy and no prior FGFR inhibitor. Screening for FGFR2 gene rearrangements will be performed at a central laboratory or locally and confirmed by a central laboratory. The primary endpoint is objective response rate based on RECIST v1.1. Secondary endpoints include duration of response, disease control rate, overall survival, progression-free survival, safety, and health-related quality of life.

Keywords: Intrahepatic cholangiocarcinoma (iCCA); FGFR2 gene rearrangements; TAS-120