

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* 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

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