TPS4220 **Poster Session**

A phase 2, randomized, multicenter study of adjuvant adebrelimab plus capecitabine in resected cholangiocarcinoma with high-risk factors: ACHIEVE.

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Background: Cholangiocarcinoma is a rare and aggressive group of gastrointestinal cancers. For early-stage disease following curative resection, capecitabine is a category 1 recommendation for adjuvant therapy for biliary tract cancer (BTC) according to the NCCN guidelines. However, recurrence rates remain high. For example, the BILCAP study reported a 5-year recurrence-free survival (RFS) rate of 34% with adjuvant capecitabine. Based on cholangiocarcinoma-specific cohort data from the Hepatobiliary Center, The First Affiliated Hospital of Nanjing Medical University, the 1-year RFS rate for intrahepatic cholangiocarcinoma (ICC) and hilar cholangiocarcinoma (HCCA) with high-risk factors is approximately 50% (unpublished data), highlighting a substantial unmet medical need. Immunotherapy has shown efficacy as adjuvant therapy in other cancer types. Results from the TOPAZ-1 and KEYNOTE-966 studies support the combination of immunotherapy and chemotherapy for advanced BTC, including locally advanced non-metastatic disease. Adebrelimab, a PD-L1 inhibitor, has shown promising results in several cancers. In China, it is approved for first-line treatment of extensive-stage small cell lung cancer with chemotherapy. The ACHIEVE study will assess the efficacy of adebrelimab plus standard adjuvant chemotherapy in ICC/HCCA patients after curative resection with high-risk factors. **Methods:** ACHIEVE is a Phase 2, randomized, open-label, multicenter study designed to assess the efficacy and tolerability of adebrelimab administered intravenously every three weeks for one year in combination with capecitabine (8 cycles) as adjuvant therapy for ICC or HCCA after curative resection. The study will enroll about 120 adult patients with histologically confirmed ICC or HCCA who have undergone complete resection (R0). Eligible participants must have an ECOG performance status of 0–1, confirmed complete response (CR) on imaging 4–8 weeks post-surgery, and at least one high-risk factor. High-risk factors are defined as follows: ICC: Single tumor $>$ 5 cm, multiple tumors, liver capsule breach, vascular invasion, regional lymph node metastasis; HCCA: Tumor invasion into surrounding tissues, vascular invasion, regional lymph node metastasis. Key exclusion criteria include locally advanced, unresectable, or metastatic disease at diagnosis and prior anti-cancer therapy before surgery. The primary endpoint is the 1-year recurrence-free survival rate (RFSR). Key secondary endpoints include overall survival (OS) and RFS, minimal residual disease (MRD), and patient-reported tolerability, and safety. Enrollment has begun, with six sites in mainland China participating. Clinical trial information: NCT06607276. Research Sponsor: None.