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HEPATOBILIARY CANCER

A phase II randomized placebo-controlled study investigating the combination of yiv-906 and sorafenib (SORA) in HBV (+) patients (Pts) with advanced hepatocellular carcinoma (HCC).

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Abstract Disclosures

Abstract

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Background: First-line systemic treatment options for advanced HCC pts are limited to the multi-targeted tyrosine kinase inhibitors, SORA and lenvatinib. Both agents improve outcomes for pts with advanced disease, but are associated with increased rate of grade ≥ 3 treatment-related adverse events. YIV-906 (PHY906, KD018) is derived from Huang-Qin-Tang, a traditional Chinese medicine documented 1800 years ago to treat gastrointestinal ailments. Preclinical data indicate YIV-906 increases inflammation in the tumor microenvironment by M1 macrophages activation/proliferation resulting in HCC tumor rejection *in vivo* and reduces SORA associated toxicity. Clinical experience

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with YIV-906 plus SORA suggests safety and potential clinical benefit to HCC pts with chronic HBV infection. **Methods:** This is a proof-of-concept, international, multicenter, double-blind, placebo-controlled, randomized phase 2 study designed to compare the efficacy of YIV-906 and SORA to SORA alone in advanced HCC pts (NCT04000737). Key eligibility criteria include age ≥ 18 years, HBV-associated HCC, ≥ 1 measurable untreated lesion, Child-Pugh A liver function, and no prior systemic therapy. An estimated 125 pts will be randomized 2:1 to receive the investigational (YIV-906 plus SORA) or control (placebo plus SORA) arm until disease progression or unacceptable toxicity. Pts will be stratified by metastatic status (extrahepatic/vascular invasion vs none) and ECOG performance status (0 vs. 1). The primary endpoint is progression-free survival (PFS). Secondary endpoints include objective response rate and disease control rate by mRECIST, time to progression, overall survival, quality of life, and safety by CTCAE version 4.0. Translational correlatives include pharmacokinetics, effects on oral/gut microbiota, and exploratory soluble biomarkers analysis. For the primary endpoint, sample size of 41 pts in control arm and 84 pts in the investigational arm achieves 90% power at a 0.05% significance level to detect a hazard ratio of 0.5 assuming the median PFS of the control SORA arm is 3.6 months and that of the combination arm is 7.3 months. Clinical trial information: NCT04000737.

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