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HEPATOBIILIARY 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

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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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N. B. Leighl, *J Clin Oncol*, 2016

Efficacy and safety of first-line bevacizumab (Bv) and cisplatin/gemcitabine (CG) in elderly patients (pts) with advanced non-small cell lung cancer (NSCLC) in the BO17704 study (AVAL) N. B. Leighl et al., *J Clin Oncol*, 2016

Final safety results of BO17704 (AVAL): A phase III randomized study of first-line bevacizumab (Bv) and cisplatin/gemcitabine (CG) in patients (pts) with advanced or recurrent nonsquamous non-small cell lung cancer (NSCLC)
V. Hirsh et al., *J Clin Oncol*, 2016

Biological activity of bevacizumab and erlotinib in patients with

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 $\geq$ 18 years, HBV-associated HCC, $\geq$ 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 correlates 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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advanced hepatocellular carcinoma (HCC)
A. O. Kaseb, J Clin Oncol, 2016

Docetaxel plus carboplatin with or without levofloxacin prophylaxis in elderly patients (pts) with advanced non-small cell lung cancer (NSCLC): The APRONTA trial
W. Schuetz et al., J Clin Oncol, 2016

Randomised, multicentre prospective trial of transarterial chemoembolisation (TACE) plus sorafenib as compared with TACE alone in patients with hepatocellular carcinoma: TACTICS trial
Masatoshi Kudo et al., Gut, 2019

Comparison and analysis of the efficacy of drug therapy for liver cancer
Philippe Merle et al., Hepatoma Research-OAE Publishing, 2020

Results from AMBER, a randomized phase 2 study of bevacizumab and bortezomib versus bortezomib in relapsed or refractory multiple myeloma
Darrell White et al., Cancer, 2012

Treating Hepatitis B: How to Combine Western Pharmacotherapy with Traditional Chinese Medicine
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Randomized phase 2 trial of erlotinib in combination with high-dose celecoxib or placebo in patients with advanced non-small cell lung cancer
Karen L. Reckamp et al., Cancer, 2015

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