



Yiviva Announces Dosing of First Patient in Phase 2b Study of First-Line YIV-906 Plus Sorafenib Combination Therapy in the Treatment of Hepatocellular Carcinoma

*- First-in-class oncology therapeutic candidate YIV-906 applies an integrative systems biology approach -
- Global study to evaluate efficacy, safety, and quality of life in patients with hepatitis B-positive hepatocellular carcinoma -*

NEW YORK and SHANGHAI, China, April 06, 2020 (GLOBE NEWSWIRE) -- Yiviva today announced that the first patient has been dosed in a Phase 2b study of YIV-906 in combination with sorafenib in the treatment of patients with hepatitis B-positive hepatocellular carcinoma (HCC). YIV-906 is a novel, proprietary therapeutic candidate based on molecular profiling of extracts identified from use in traditional botanical medicine. YIV-906 has demonstrated that it can potentiate the anti-tumor activity of sorafenib, enhance innate and adaptive immune function in the tumor microenvironment, protect cells of the gastrointestinal tract by reducing inflammation mediated by IL-6, NF-kappaB, COX2, iNOS, and accelerate regeneration of damaged gastrointestinal tissue by promoting progenitor and stem cell growth via the Wnt signaling pathway.

"Patients and providers are eager to have evidence-based systemic treatment options for cancer, such as YIV-906," commented Edward Chu, M.D., Chief of the Division of Hematology and Oncology, Deputy Director at the UPMC Hillman Cancer Center, University of Pittsburgh School of Medicine and senior advisor to Yiviva. "YIV-906 applies a novel systems biology approach that has been shown in preclinical and preliminary clinical studies to enhance immune function in the tumor microenvironment and protect gastrointestinal tissue. Observations of the effects of YIV-906 in proof of concept clinical studies provide a compelling rationale for conducting this large global study in the first-line treatment setting. In addition, patients with hepatitis B-positive HCC represent a population with particularly limited treatment options where the YIV-906 approach could have a particularly significant impact on care."

"The development of YIV-906 is a state-of-the-art approach using modern science, bioinformatics, and current GMP manufacturing to develop a precisely engineered botanical medicine," commented Yun Yen, M.D., Ph.D., Co-Global PI Coordinator of the YIV-906 study and former President of Taipei Medical University. "The components of YIV-906 have been selected for their expected effects across multiple targets when administered as a complex mixture in combination. Given the major need for better treatments for patients with liver cancer, and the safety and efficacy profile of YIV-906 as seen to date, we look forward to the results of this global study. This could lead to new therapeutic strategies to treat cancer patients holistically."

The randomized, placebo-controlled Phase 2b study of YIV-906 is evaluating efficacy, safety, and quality of life in patients with hepatitis B-positive HCC. The clinical study is designed to enroll approximately 125 patients at 20 sites in the U.S., mainland China, Hong Kong, and Taiwan, including Memorial Sloan Kettering Cancer Center, Taipei Medical University, Queen Mary Hospital in Hong Kong and the China National Cancer Center in Beijing. Patients will be randomized 2:1 to either the study arm (YIV-906 plus sorafenib) or control arm (placebo plus sorafenib). The primary endpoint of the study is an evaluation of progression free survival. Secondary endpoints include safety and quality of life assessments and additional measures of clinical efficacy, including time to progression, overall survival, objective response rate and disease control rate. Change of quality of life will be assessed according to HCC18 and EORTC QLQ-C30 assessments. Additional information is available at <https://clinicaltrials.gov/ct2/show/NCT04000737>.

About YIV-906

YIV-906 (also PHY906 or KD018) is a therapeutic candidate comprised of a proprietary cGMP botanical extract of four herbs inspired by a traditional Chinese medicine formulation used for over a millennium. YIV-906 has the potential to be developed as a platform oncology therapeutic when administered in combination with chemotherapy, immunotherapy and radiation therapies, in multiple cancer indications. YIV-906 has been shown to enhance immune function in the tumor microenvironment (by polarizing M1 macrophages and activating T cells), protect the gastrointestinal tract (by inhibiting inflammation via IL-6, NF-kappa-B, COX2, and iNOS pathways) and promote intestinal tissue repair (by increasing activity and expression of components of the Wnt signaling pathway). YIV-906 has been observed to enhance the anti-tumor activity of sorafenib in preclinical models of hepatocellular carcinoma and has shown promise in preliminary clinical studies in liver, pancreatic, colorectal and rectal cancers. YIV-906 has been granted Orphan Drug designations from the U.S. Food and Drug Administration (FDA) for development of YIV-906 in the treatment of hepatocellular carcinoma and pancreatic cancer. Yiviva holds worldwide intellectual property for YIV-906 including 32 patents related to methods of use, manufacturing and quality control. YIV-906 is being developed for approval under the U.S. FDA Botanical Drug regulatory pathway.

About Yiviva

Yiviva is a clinical stage biotechnology company developing multi-target botanical therapeutics using a systems biology approach, focused on cancer, inflammatory and chronic diseases. The Yiviva STAR (signal transduction, activity and response) discovery platform accelerates the identification of botanical therapeutics that influence immune function, inflammatory responses, cell growth and metabolic functions and hormone activity. Yiviva applies patented, mechanism-based quality control linked to biological activity to satisfy established regulatory requirements for complex products. The company was launched with Yale University as a co-founder and co-founders include Yung-Chi Cheng, Ph.D., with teams in New York, New Haven, Connecticut and Shanghai. For further information, please visit <https://yiviva.com>.

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