

BioMed Valley Discoveries Announces First Patient Dosed in Phase II Combination Trial with Ulixertinib (BVD-523), its First-in-Class and Best-in-Class ERK Inhibitor, in Combination with Hydroxychloroquine

September 12, 2022

KANSAS CITY, Mo., Sept. 12, 2022 – BioMed Valley Discoveries (BVD) announced that the first patient has been dosed in a phase II clinical trial of ulixertinib (BVD-523) in combination with hydroxychloroquine (HCQ). Ulixertinib is a first-in-class and best-in-class ERK inhibitor, with this clinical trial focusing on patients with advanced gastrointestinal malignancies and mutations in the MAPK pathway. This study builds upon the finding of the phase I study of the combination, which was completed at Huntsman Cancer Institute at the University of Utah.

“Combining an ERK inhibitor with an autophagy inhibitor is anticipated to take advantage of the finding that tumors may become addicted to autophagy for survival in context of MAPK inhibition” said Brent Kreider, Ph.D., President of BioMed Valley Discoveries. “Given the favorable safety profile and efficacy seen with ulixertinib monotherapy, we believe that the combination with hydroxychloroquine has the potential to provide significant benefit to patients with advanced gastrointestinal malignancies.”;

The Phase II efforts build on a successful Phase Ib evaluating ulixertinib monotherapy as a novel targeted cancer treatment in cohorts of patients with genetic alterations that result in aberrant MAPK pathway signaling. Results from phase Ib demonstrated ulixertinib has an acceptable safety profile and early evidence of clinical activity against a wide range of RAS/MAPK pathway-driven cancers, including atypical alterations in BRAF.

In addition to targeting the terminal node of the RAS/MAPK pathway, ulixertinib’s highly selective kinase inhibition profile is expected to provide potential impact across a number of tumor types in both monotherapy and combination. Previous efforts have also established a recommended phase 2 dose in combination with palbociclib, with additional combination efforts ongoing.

About ulixertinib (BVD-523): Ulixertinib is a first-in class and best-in class small molecule inhibitor of extracellular signal-regulated kinase (ERK) family kinases (ERK1 and ERK2) that is being developed as a novel anti-cancer drug. ERK kinases are downstream components of the mitogen-activated protein kinase (MAPK) signaling cascade (RAS-RAF-MEK-ERK). Ulixertinib has demonstrated promising early efficacy for patients with tumors harboring alterations in the MAPK pathway.

About the study: This is an open-label, multicenter, prospective phase II basket trial assessing the efficacy of ulixertinib in combination with hydroxychloroquine in patients with advanced gastrointestinal malignancies. All patients recruited must have a mitogen-activated protein kinase (MAPK) activating mutation to be deemed eligible for trial participation. Each disease-based basket will open to enrollment in two-stages and includes pancreatic, colorectal, esophageal, gastric and cholangiocarcinomas. (Clinicaltrials.gov Number NCT05221320)

About BioMed Valley Discoveries (BVD): BioMed Valley Discoveries is a clinical stage biotechnology company focused on addressing unmet medical needs in a variety of therapeutic and diagnostic areas. In addition to the ERK inhibitor, BVD’s portfolio includes an oncolytic bacteria that has completed enrollment for a Phase I study, and two early-stage antibodies targeting the tumor microenvironment.

Operating since 2007, BioMed Valley Discoveries was established by Jim Stowers Jr., founder of the asset management firm American Century Investments, and his wife Virginia, to advance new medical innovations to improve the lives of patients with difficult-to-treat diseases. BVD is owned by a supporting

organization of the Stowers Institute for Medical Research, a non-profit, basic biomedical research organization. Since 2000, the endowment of the Stowers Institute has received over \$1.7 billion in dividend payments from American Century. The Institute has invested a portion of its endowment in BVD, whose profits accrue to the benefit of the Institute. For more information, visit www.biomed-valley.com.

Media Contact

Joe Chiodo, Head of Media Relations

724-462-8529

Joe.chiodo@stowers.org