BIOMED VALLEY
DISCOVERIES

**BioMed Valley Discoveries' ulixertinib (BVD-523), a first-in-class ERK inhibitor cancer therapy, receives Fast Track designation and launches Phase II trial in collaboration with Cmed and Strata Oncology**

**July 28, 2020**

Kansas City, MO. – BioMed Valley Discoveries (BVD), a clinical stage biotechnology company, announces the receipt of Fast Track designation from the US Food and Drug Administration (FDA) for investigation of the ERK inhibitor ulixertinib (BVD-523) as a treatment for patients with non-colorectal, solid tumors that harbor BRAF mutations G469A/V, L485W, or L597Q. BVD has launched a Phase II multi-center study of ulixertinib for patients with advanced malignancies harboring these atypical (non-V600) BRAF alterations or a MEK alteration.

The Phase II effort builds on a successful Phase Ib evaluating ulixertinib as a novel targeted cancer treatment in cohorts of patients with specific genetic alterations that result in aberrant MAPK pathway signaling. Results from Phase Ib showed that ulixertinib has an acceptable safety profile and early evidence of clinical activity against a wide range of tumor types exhibiting mutations in the MAPK pathway, including atypical alterations in BRAF.

BVD is pleased to announce that Cmed, Inc., will serve as the contract research organization (CRO) for the Phase IIb study. BVD is also collaborating with Strata Oncology to identify and obtain study patients with Strata's Precision Oncology Network. This network of trial-ready health systems features a database of matched trial candidates that will allow for rapid and efficient identification of potential patients.

David Chao, PhD, president and CEO of BVD, comments, "We are pleased with the receipt of Fast Track designation for ulixertinib and delighted to collaborate with Cmed and Strata to develop this promising first-in-class ERK inhibitor."

This study (NCT04488003) is currently expected to begin enrollment in Q3 2020.

**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, including atypical (non-V600) BRAF alterations, for which there are currently no approved targeted agents.

**About Fast Track status:** Fast Track is a designation by the FDA of an investigational drug for expedited review to facilitate development of drugs which treat a serious or life-threatening condition and fill an unmet medical need. Fast Track status entails eligibility for Accelerated Approval and Priority Review if certain criteria are met as well as more frequent interactions with the FDA.

**About the study:** This Phase II study expands upon the ulixertinib Phase I signal to evaluate the utility of ulixertinib to treat patients with tumors harboring an atypical BRAF alteration. Furthermore, the potential to treat MEK1/2 mutant cancers will also be explored. This patient population is rare (<1% of cancers), however a strong scientific rationale exists to treat patients harboring putatively activating MEK1/2 alterations with ERK inhibition. Part A of the trial is tumor histology agnostic, with patients enrolled in one of six groups based on their tumor alteration. Part B of the trial is tumor histology specific, enrolling patients with one of up to three specified tumor histologies based on evolving part A data.

**About Cmed:** Cmed, established for 20 years, is a global technology-led full-service CRO specializing in complex disease areas, particularly oncology, immuno-oncology, cell therapy, and other specialty therapeutics areas. Cmed has built a reputation for delivering these clinical trials with expertise, and a personalized, flexible approach, and a mission to contributing to the development of innovative medicines for the benefits of the patients. Cmed has a strong data management and statistics heritage.

As well as being a Functional Service Provider of these services, via its Cmed Technology business (part of Cmed Group), Cmed has developed and uses an advanced, enterprise, cloud based clinical data system, encapsia®. encapsia delivers a complete solution to gather and manage multiple live clinical data sources and apply real-time data management, sophisticated visualizations, analytics, and AI. Client benefits include informed trial progress, deep insights into their data to support timely management decisions, and particularly relevant with the disruption caused by the COVID-19 pandemic, able to support remote, decentralized, and virtual trial conduct. For more information, visit www.cmedresearch.com and www.encapsia.com or contact Info@cmedgroup.com.

**About Strata Oncology:** Strata Oncology, Inc. is a precision medicine company dedicated to transforming cancer care by building a platform to systematize precision oncology across a network of health systems and pharma companies. Strata empowers health systems to deliver a cost-effective, system-wide, precision oncology program, one that integrates cutting-edge molecular profiling and precision therapy trials with routine care, so that all advanced cancer patients have the opportunity to benefit. This large network of trial-ready health systems provides a mechanism to rapidly and predictably enroll precision therapy trials. For more information, visit www.strataoncology.com.

**About the Strata Precision Oncology Network:** The Strata Precision Oncology Network ("Network"), led by Strata Oncology, is a collaborative network of leading health systems that believe in deploying a clinical-research driven model for precision medicine that enables continuous learning to drive research and clinical care. The Network consists of 25 leading health systems that have demonstrated a commitment to standardizing tumor molecular profiling and precision therapy trials, providing a platform to accelerate drug approvals and catalyze new clinical research opportunities. The Strata Trial serves as the foundation of this approach by providing a standardized genomic testing protocol to deliver precision oncology system-wide.

**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, a selective phosphoinositide 3-kinase gamma inhibitor in late preclinical testing, 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 $1.5 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

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