xCures announces the launch of a Compassionate Use program for ulixertinib (BVD-523)

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BioMed Valley Discoveries' first-in-class ERK inhibitor available through newly opened compassionate use protocol.

September 28, 2020 – San Francisco, CA. – xCures, a clinical study platform provider, announces the US Food and Drug Administration (FDA) granted their IND for an intermediate Expanded Access Program (EAP) for the ERK inhibitor ulixertinib (BVD-523).

Ulixertinib is being developed by BioMed Valley Discoveries (BVD), a clinical stage biotechnology company, as a treatment for patients with MAPK pathway aberrant cancer, including but not limited to KRAS, NRAS, HRAS, BRAF, MEK, and ERK, mutations.

The EAP is open across the United States to adolescent and adult cancer patients who cannot access an open clinical trial for the investigation of ulixertinib (BVD-523).

"xCures prospective real-world evidence generation capability transforms managed access programs such as the ulixertinib expanded access program by making them an efficient way for physicians and patients to gain access to promising therapies when clinical trials are not an option," says Mika Newton, CEO of xCures, Inc. "xCures' programs uniquely capture high-value evidence related to the safety and efficacy from this expanded set of patients."

This intermediate-sized expanded access program (NCT04566393) is currently open and available for physicians interested in treating their patients. Physicians can reach out to expandedaccess@xcures.com for more information. Patients can register and find more information at enroll.xcures.com/uli-eap or receive additional information via xCures patient advocacy partner Cancer Commons (www.cancercommons.org).

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 Expanded Access:

Expanded access, which is often called "compassionate use," is the use of an unapproved drug for treatment of patients with serious or life-threatening illnesses outside of a clinical trial. Expanded access is subject to oversight from the US FDA in accordance with the regulations outlined in 21 CFR 312.305.

About the Program:

This Expanded Access program provides ulixertinib for compassionate use in advanced cancer patients with a MAPK pathway-altered solid tumor(s) who have exhausted available therapies. The protocol aims to collect sufficient information about the patient's treatment to provide a complete and accurate case report to health authorities using real-world data collection to assess response to treatment, safety, tolerability, and quality-of-life.

About xCures:

xCures Inc. provides clinical study platforms that use AI/ML algorithms to support tumor boards with the allocation of cancer patients to optimal treatment programs and clinical trials. The xCures platform prospectively generates Real World Evidence for investigational and approved therapies. Patient EMR data is continuously collected, stored, and structured into a regulatory-grade format ready for use in submissions to the FDA. For more information, visit www.xcures.com and or contact info@xcures.com.

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 https://www.biomed-valley.com.