



## **Biomed Valley Discoveries Announces First Patient Dosed in Phase 2 Study of Its First-in-Class ERK 1/2 Inhibitor Ulixertinib in People with Histiocytosis**

*-- Investigator-initiated trial follows observation of early efficacy signals in multiple histiocytosis patients who were administered ulixertinib under BVD's compassionate use program --*

KANSAS CITY, Mo., August 13, 2024 – Biomed Valley Discoveries (BVD), a clinical-stage biotechnology company guided by its founders' intent of bringing hope for life to patients, today announced that the first patient has been dosed in a Phase 2 study of ulixertinib, BVD's highly selective, first-in-class ERK 1/2 inhibitor. The study will evaluate the safety and efficacy of ulixertinib monotherapy for the treatment of histiocytosis – a group of rare, cancer-like disorders characterized by an abnormal proliferation of a type of white blood cells called histiocytes – in patients ages 12 and older who have progressed on or cannot tolerate other therapies ([NCT06411821](https://clinicaltrials.gov/ct2/show/study/NCT06411821)).

Eli Diamond, M.D., neuro-oncologist and early drug development specialist at Memorial Sloan Kettering Cancer Center, is the lead principal investigator for this investigator-initiated trial (IIT). The IIT was initiated following the observation of durable efficacy signals in multiple histiocytosis patients who were administered ulixertinib under BVD's compassionate use program, per the request and under the care of Dr. Diamond.

“There is a tremendous need for new treatment options for patients with histiocytosis, many of whom progress on or cannot tolerate existing treatments,” said Dr. Diamond. “I am encouraged by the compassionate use cases in which ulixertinib provided meaningful clinical benefit for histiocytosis patients who were not responding to other therapies. Based on these observations, my collaborators and I look forward to further investigating ulixertinib in this patient population and believe it has the potential to offer a much-needed new treatment approach to overcome resistance mechanisms.”

Histiocytosis can cause tumors throughout the body, fractures and bone lesions, mental deterioration, lung disease, hormonal abnormalities, and many other systemic symptoms. The MAPK signaling pathway – which comprises a sequential cascade of four key signaling nodes – RAS, RAF, MEK and ERK – is implicated in many cases of histiocytosis. There are limitations to the MAPK pathway treatments currently being deployed, including emergence of resistance to treatment. Direct inhibition of ERK, the final node of the MAPK pathway, represents an important potential strategy to overcome these challenges and limitations. There are currently no approved ERK inhibitors for histiocytosis or any additional indications.

“We are pleased that the ulixertinib compassionate use cases have provided actionable clinical insights to support the initiation of this study, which may result in significant benefits for a greater number of patients in need, and we applaud Dr. Diamond’s commitment and extensive efforts to find therapeutic solutions to help patients impacted by this difficult disease,” said Brent Kreider, Ph.D., president of BVD. “We believe that treatment with our investigational first-in-class ERK inhibitor, ulixertinib, has the potential to bring new hope for life to patients with histiocytosis, in line with our mission and founders’ intent.”

Ulixertinib is currently under investigation for more than 10 solid and liquid tumor indications, across both pediatric and adult indications, and as both a monotherapy and in combination with other cancer treatments. To learn more, visit <https://biomed-valley.com/ulixertinib/>.

### **About Biomed Valley Discoveries**

Biomed Valley Discoveries (BVD) is a clinical-stage biotechnology company on a quest to make a meaningful difference for patients and their families. Founded by Jim and Virginia Stowers, BVD is exclusively guided by its founders’ intent of bringing hope for life to patients. As part of the Stowers Group of Companies, BVD receives stable and sustainable resources through private institutional funding via American Century Investments, an asset management firm founded by Jim Stowers. Because of this innovative funding model, BVD has created a purposefully reimagined approach to every aspect of business operations and the pursuit of groundbreaking medicines. BVD is currently advancing three novel oncology programs, including: ulixertinib, a highly selective, first in class ERK 1/2 inhibitor; TEM8-directed antibody drug conjugates (ADCs); and clostridium novyi-NT, a cancer-fighting bacteria. To learn more, visit BVD’s [website](#) or connect on [LinkedIn](#).

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