Biomed Valley Discoveries Announces First Patient Dosed in Phase 1/2 Combination Study of Ulixertinib with Ruxolitinib (Jakafi®) in Patients with Myelofibrosis

-- Dual targeting of JAK 1/2 (ruxolitinib) and ERK 1/2 (ulixertinib) may represent a novel treatment approach for myelofibrosis and possibly other myeloproliferative neoplasms

KANSAS CITY, Mo., [April 28, 2025] – 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 1/2 combination study of ulixertinib, BVD's highly selective, first-in-class ERK 1/2 inhibitor with ruxolitinib, a JAK1/JAK2 inhibitor for the treatment of myelofibrosis, a rare type of bone marrow cancer that disrupts the body's normal production of blood cells.

Raajit Rampal, M.D., Ph.D., a hematologist-oncologist with Memorial Sloan Kettering Cancer Center who specializes in the treatment of myeloproliferative neoplasms and leukemia, is the lead principal investigator for this investigator-initiated trial.

"We're thrilled to announce the milestone of first patient dosed in this trial, and grateful for the opportunity to collaborate with Dr. Rampal and Incyte to explore the potential of ERK inhibition as a complement to JAK inhibition for the treatment of patients with myelofibrosis," said Brent Kreider, Ph.D., President of BVD. "This trial helps further our commitment to fully interrogate the potential of direct ERK inhibition to address unmet patient needs in various cancer settings where MAPK signaling is implicated."

"JAK inhibitors have transformed the treatment of myelofibrosis and other myeloproliferative neoplasms. There is now a significant focus to enhance the therapeutic efficacy of JAK inhibition in these diseases through combination approaches," said Dr. Rampal. "Research suggests that compensatory activation of MAPK signaling may impede the efficacy of JAK inhibition. We look forward to evaluating the dual targeting of JAK and ERK, the terminal node of the MAPK pathway, in this Phase 1/2 study and the potential benefits this combination strategy may deliver for patients."

The Phase 1/2 study (NCT06773195) will evaluate the safety, tolerability and efficacy of ulixertinib in combination with ruxolitinib in adult patients 18 years and older who exhibit persistent disease after at least three months of receiving a stable dose of ruxolitinib monotherapy. Patients with primary myelofibrosis, post-essential thrombocythemia (ET) myelofibrosis, post-polycythemia vera (PV) myelofibrosis, or post-pre-fibrotic myelofibrosis are eligible for the trial.

Jakafi is a registered trademark of Incyte.

Dr. Rampal has financial interests related to Incyte.

About Ulixertinib

Ulixertinib, a highly selective first-in-class ERK 1/2 inhibitor, 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 **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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