

## Evrenzo gets approval in Japan to treat anemia associated with CKD

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Astellas Pharma Inc. and FibroGen, Inc. have announced that Japan's Ministry of Health, Labour and Welfare (MHLW) approved Evrenzo® (generic name: roxadustat) for the treatment of anemia associated with chronic kidney disease (CKD) in dialysis patients.

Roxadustat is a first-in-class orally administered inhibitor of hypoxia-inducible factor (HIF) prolyl- hydroxylase that corrects anemia by a mechanism of action that is different from that of erythropoiesis-stimulating agents (ESAs). As a HIF-PH inhibitor, roxadustat activates a response that occurs naturally when the body responds to reduced oxygen levels in the blood. The response activated by roxadustat involves the regulation of multiple, complementary processes to promote erythropoiesis and increase the blood's oxygen-carrying capacity.

"Evrenzo® is a valuable new treatment option for dialysis patients with CKD anemia," said Bernhardt G. Zeiher, M.D., Chief Medical Officer, Astellas. "Astellas is committed to improving the health of people worldwide and expanding treatment options, especially within the dialysis community where there is high-unmet need. We are delighted to bring this important new treatment option to both patients suffering from, and healthcare professionals treating, this debilitating condition."

"We appreciate the commitment and focus of our partner Astellas as we work together to bring a new therapy to CKD anemia patients on dialysis in Japan," said K. Peony Yu, M.D., Chief Medical Officer, FibroGen. "With this approval in Japan, NDA approval in China, and EU MAA and US NDA preparations underway, we are another step closer to our goal of addressing the significant unmet medical need of patients living with anemia of CKD, worldwide."

The approval is based on four Phase 3 studies conducted in CKD anemia patients on dialysis in Japan. The studies demonstrated that roxadustat was effective at raising hemoglobin and that it was well-tolerated. This marks the first approval for roxadustat through the Astellas and FibroGen collaboration.