

**Brand Name:** Evrenzo

**Generic:** roxadustat

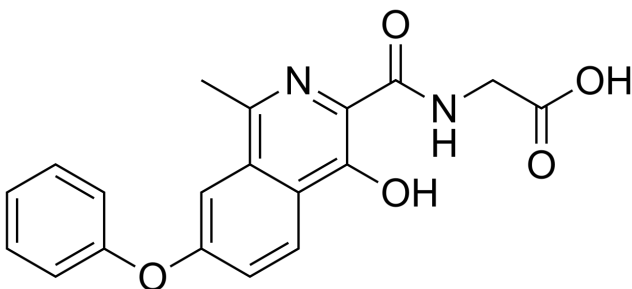
**Type:** small molecule

**Year Accepted/Phase:** 2021

### **Mechanism:**

Roxadustat stabilizes hypoxia-inducible factor (HIF), a transcription factor that stimulates erythropoiesis by increasing the production of endogenous erythropoietin, enhancing iron absorption and utilization, and reducing hepcidin levels.

### **Chemical Structure:**



### **Indication:**

Evrenzo is indicated for the treatment of anemia due to chronic kidney disease in adult patients not on dialysis and on dialysis.

## Clinical trials:

### **ALPINE Trial (Phase III)**

**Pubmed:** <https://pubmed.ncbi.nlm.nih.gov/33630072/>

**Purpose:** Evaluate the efficacy and safety of roxadustat in treating anemia in CKD patients not on dialysis.

**Dates:** Conducted from 2013 to 2016.

**Results:** The ALPINE trial demonstrated that roxadustat effectively increased hemoglobin levels compared to placebo. Roxadustat-treated patients had significant improvements in hemoglobin levels, reducing the need for red blood cell transfusions.

**Impact:** This trial supported the use of roxadustat in non-dialysis-dependent CKD patients, providing evidence of its efficacy and safety in this population.

### **ROCKIES Trial (Phase III)**

**Pubmed:** <https://pubmed.ncbi.nlm.nih.gov/35361724/>

**Purpose:** Assess the efficacy and safety of roxadustat compared to epoetin alfa in CKD patients on dialysis.

**Dates:** Conducted from 2014 to 2017.

**Results:** The ROCKIES trial showed that roxadustat was non-inferior to epoetin alfa in increasing and maintaining hemoglobin levels in dialysis-dependent CKD patients. Roxadustat also demonstrated a comparable safety profile to epoetin alfa.

**Impact:** The results of the ROCKIES trial provided substantial evidence for the approval of roxadustat as a treatment option for anemia in CKD patients on dialysis.

### **HIMALAYAS Trial (Phase III)**

**Pubmed:** <https://pubmed.ncbi.nlm.nih.gov/33629100/>

**Purpose:** Evaluate the efficacy and safety of roxadustat in treating anemia in incident dialysis patients (those who have recently started dialysis).

**Dates:** Conducted from 2014 to 2017.

**Results:** The HIMALAYAS trial demonstrated that roxadustat effectively increased hemoglobin levels in incident dialysis patients compared to placebo. Roxadustat-treated patients had significant improvements in hemoglobin levels and reduced the need for erythropoiesis-stimulating agents (ESAs).

**Impact:** This trial supported the use of roxadustat in incident dialysis patients, highlighting its efficacy and safety in a newly dialysis-dependent population.

**SIERRAS Trial (Phase III)**

**Pubmed:** <https://pubmed.ncbi.nlm.nih.gov/34307977/>

**Purpose:** Assess the long-term efficacy and safety of roxadustat in treating anemia in CKD patients on dialysis.

**Dates:** Conducted from 2015 to 2018.

**Results:** The SIERRAS trial showed that roxadustat maintained hemoglobin levels over the long term in dialysis-dependent CKD patients. The trial confirmed the safety and efficacy of roxadustat for sustained use in this population.

**Impact:** The long-term data from the SIERRAS trial reinforced the suitability of roxadustat for chronic use in managing anemia in dialysis-dependent CKD patients.