**ASCEND-NHQ: Anemia Studies in CKD: Erythropoiesis via a Novel PHI Daprodustat in Non-Dialysis participants evaluating Hemoglobin and Quality of life**

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**Study Objectives**
To compare the efficacy of daprodustat to placebo on mean change in Hgb levels  
To compare the proportion of participants achieving increases in Hgb when treated with daprodustat versus placebo  
To compare daprodustat to placebo for health related quality-of-life

**Inclusion Criteria**
Patients are eligible to be included in the study if they meet all of the following criteria:
- Age 18 years or older  
- CKD stages 3, 4 or 5  
- Hgb 8.5 - 10.5 at screening & 8.5 - 10 at randomization  
- May receive up to one IV iron dose within the 8 weeks prior to screening  
- May be on stable maintenance oral iron

**Exclusion Criteria**
Patients are excluded if they meet any of the following criteria:
- Impending need to initiate dialysis within 180 days after randomization.  
- Planned living-related or living-unrelated kidney transplant.  
- Transferrin saturation (TSAT) <15 percent (Screening only).  
- Ferritin <50 nanograms per milliliter (ng/mL) (Screening only).  
- rhEPO or rhEPO analogue use within the 8 weeks prior to screening.  
- History of transfusion within the 8 weeks prior to screening.
- History of bone marrow aplasia or pure red cell aplasia (PRCA).
- Megaloblastic anemia (untreated pernicious anemia and folate deficiency), thalassemia major, sickle cell disease or myelodysplastic syndrome.
- Evidence of actively bleeding gastric, duodenal, or esophageal ulcer disease or clinically significant gastrointestinal (GI) bleeding <= 8 weeks prior to screening.
- History of severe allergic or anaphylactic reactions or hypersensitivity to excipients in the investigational product.
- Use of strong inhibitor of CYP2C8 (for example, gemfibrozil) or strong inducers of CYP2C8 (for example, rifampin/rifampicin).
- Ferric citrate use within 4 weeks prior to randomization.
- Use of another investigational agent within 30 days or within five half-lives of the investigational agent (whichever is longer) or currently participating in a study of an investigational device prior to screening through to randomization (Day 1).
- Any prior treatment with daprodustat >30 days.
- MI or acute coronary syndrome within the 8 weeks.
- Stroke or transient ischemic attack within the 8 weeks.
- Chronic Class IV heart failure (NYHA).
- QT interval corrected by Bazett's formula (QTcB) >500 milliseconds (msec) or QTcB >530 msec in subjects with bundle branch block. There is no corrected QT interval (QTc) exclusion for subjects with a predominantly paced rhythm.
- Alanine transaminase (ALT) >2x upper limit of normal (ULN).
- Bilirubin >1.5xULN.
- Current unstable liver or biliary disease.
- History of malignancy within the 2 years, or currently receiving treatment for cancer, or complex kidney cyst.

Affiliations & Sponsors
GlaxoSmithKline

Status
Closed to enrollment

Keywords
CKD, chronic kidney disease, anemia, non-dialysis, hemoglobin, daprodustat, recombinant human erythropoietin naïve