Full Title:  **ASCEND-ND**: Anemia Studies in CKD: Erythropoiesis via a Novel PHI Daprodustat-Non-Dialysis

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Study Objective:
- To compare daprodustat to darbepoetin alfa for cardiovascular (CV) safety (non-inferiority).
- To compare daprodustat to darbepoetin alfa for hemoglobin (Hgb) efficacy (non-inferiority).

Inclusion Criteria:
Patients are eligible to be included in the study if they meet all of the following criteria at screening and randomization:
- Age 18 to 99 (inclusive) and capable of providing informed consent
- CKD stage (confirm at screening only), HemoCue Hgb (range inclusive), Compliance with placebo [randomization (Day 1) only]
- ESAs:
  - Group 1 (not using ESAs): No ESA use within the 6 weeks prior to screening and no ESA use between screening and randomization (Day 1).
  - Group 2 (ESA users): Use of any approved ESA (see footnote in table below) for the 6 weeks prior to screening and continuing between screening and randomization
Exclusion Criteria

Patients are excluded if they meet any of the following criteria at screening and randomization (Day 1):

- CKD related criteria: On dialysis or clinical evidence of impending need to initiate dialysis within 90 days after study start (Day 1); Planned living-related or living-unrelated kidney transplant within 52 weeks after study start (Day 1).
- Anemia-related criteria: Ferritin (screening only): ≤100 ng/mL (≤100 μg/L); Transferrin saturation (TSAT) (screening only): ≤20%. If TSAT is 18-20%, then a retest using a new blood sample can be obtained within 7 days of the final laboratory report; the final retest value must be >20% to confirm eligibility; Aplasias; Untreated pernicious anemia, thalassemia major, sickle cell disease or myelodysplastic syndrome; Gastrointestinal (GI) bleeding
- CV disease-related criteria: MI or acute coronary syndrome; Stroke or transient ischemic attack; Heart failure (HF); Current uncontrolled hypertension; QTcB (Day 1): QTcB >500 msec, or QTcB >530 msec in subjects with bundle branch block
- Liver disease
- Pregnancy

Affiliations & Sponsors
GSK

Status
Open to enrollment

Keywords
Dialysis, anemia, chronic kidney disease, CKD