Hemoglobin Stability in the ASCEND-D and -ND Trials

**Aims**

To examine the management of hemoglobin (Hb) levels for patients with chronic kidney disease (CKD) receiving dialysis or not receiving dialysis treated with dopamine (Dop) or erythropoiesis-stimulating agents (ESAs).

**Background**

Hb levels in target ranges per clinical care guidelines for patients (pts) with CKD have been associated with improved outcomes.1–3 Hemoglobin stability is a key parameter for the management of chronic kidney disease (CKD) receiving dialysis or not receiving dialysis treated with Dop or ESAs in the ASCEND-D (NCT02879305) and ASCEND-ND (NCT02876835) studies.

We examined the stability of Hb levels in pts with CKD receiving dialysis or not receiving dialysis treated with Dop or ESAs in the ASCEND-D (NCT02879305) and ASCEND-ND (NCT02876835) studies.

**Methods**

ASCEND-D (NCT02879305) and ASCEND-ND (NCT02876835). Daprodustat is an oral non-erythropoietin receptor activator (NE-RAP) developed for the treatment of anemia in hemodialysis (HD) patients.4–6 Daprodustat is an oral agent available in Japan and is currently under development in the United States and the European Union.7

**Results**

**For the ASCEND-D and -ND trials, respectively:**

- A total of 2645 and 3872 pts were randomized.
- Of randomized pts, 83.8% (n=2236/2684) and 77.8% (n=3011/3872) had evaluable Hb levels during the EP and MP, respectively.

**Target Hb and Hb excursions from evaluable Hb values:**

- Most pts in both studies achieved a mean Hb within 10–11 g/dL during the EP.

**ESAs**

- ESAs: erythropoietin stimulating agents

**Conclusions**

- During the MP, the mean (SD) percentage of time Hb was ≥12 g/dL was similar in both ASCEND-D (21% [4.24], Daprodustat and 19.8% [2.22], ESA) and ASCEND-ND (21% [4.23], Daprodustat and 24.8% [2.7], ESA), respectively.

**Table 1**

<table>
<thead>
<tr>
<th>Study</th>
<th>MP (Wk 8–16)</th>
<th>EP (Wk 26–48)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study finish</td>
<td></td>
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<tr>
<td>Patients with evaluable Hb* during MP</td>
<td>1238 (83)</td>
<td>1247 (84)</td>
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<tr>
<td>(≥10% and ≥85% of evaluable Hb values)</td>
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**Responders with Hb within analysis range EP**

- Among evaluable pts, 943 (73) pts had Hb values within the analysis range for the whole EP.
- The % time within analysis range for the EP and MP was 7.5% (4.14) and 5.6% (1.46), respectively.

**Hb excursions during EP**

- The % time within analysis range for the EP and MP was 7.5% (4.14) and 5.6% (1.46), respectively.

**Conclusions**

- In both studies during the EP and MP, Hb stayed within the analysis range for a greater proportion of time in the Dapro group than the ESA group.6–7

**Figure 1**

1. Time of Hb within the analysis range during the (A) EP and (B) MP.

**Figure 2**

1. Median % of time during the MP the pts had Hb ≥12 g/dL for pts with ≥12 g/dL during the EP.

**References**


**Disclosures**

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1 George Institute for Global Health, New Delhi, India; 2HemPharmacology, University of Minnesota, Minneapolis, MN, USA; 3Renal Associates, PA, San Antonio, TX, USA; 4Washington University School of Medicine, St Louis, MO, USA; 5GSK, Collegeville, PA, USA; 6GSK, Brentford, London, UK; 7Brompton and Women’s Hospital and Harvard Medical School, Boston, MA, USA; 8WU at time of study.

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