

Document Title	Errata to the Cardiovascular and Renal Drugs Advisory Committee Sponsor Briefing Materials for roxadustat/[FG-4592]
Meeting Date:	15 July 2021
Errata Date:	30 June 2021

Purpose:

This errata was generated to correct several typographical errors present in the original briefing materials prepared by the Sponsor for the Cardiovascular and Renal Drugs Advisory Committee (CRDAC). A summary of these corrections is provided here. These corrections do not change the data analyses, interpretations, and conclusions.

The Sponsor would like to inform the CRDAC that on June 24, 2021, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) rendered a positive opinion recommending the granting of marketing authorization for roxadustat (trade name: Evrenzo) for the treatment of adult patients with symptomatic anemia associated with chronic kidney disease. The decision regarding approval will be made by the EU commission based on the CHMP positive benefit/risk recommendation and is expected in August 2021.

In this document corrections are written in red and bold text:

Page Affected	Old Version	Correction																																																																																										
Page 36 Section 1.4.3	Figure 22 Title: Pooled DD Studies: LS Mean Change from Baseline in Health-Related Quality of Life Scores at Week 28	Figure 22 Title: Pooled DD Studies: LS Mean Change from Baseline in Health-Related Quality of Life Scores at Week 12																																																																																										
Page 91 Section 5.1.2	<p>Table 19: NDD Studies: Demographic and Baseline Characteristics</p> <p>Study 608: Mean (SD) baseline eGFR \geq30 in Placebo arm: 26 (12.8)</p> <table border="1"> <thead> <tr> <th></th> <th colspan="2">Study 060</th> <th colspan="2">Study 001</th> </tr> <tr> <th></th> <th>Roxa (N=616)</th> <th>Placebo (N=306)</th> <th>Roxa (N=1384)</th> <th>Placebo (N=1377)</th> </tr> </thead> <tbody> <tr> <td>Race, n (%)</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>White</td> <td>176 (28.6)</td> <td>99 (32.4)</td> <td>623 (45.0)</td> <td>611 (44.4)</td> </tr> <tr> <td>Black/African American</td> <td>76 (12.3)</td> <td>28 (9.2)</td> <td>112 (8.1)</td> <td>115 (8.4)</td> </tr> <tr> <td>Asian</td> <td>310 (50.3)</td> <td>151 (49.3)</td> <td>544 (39.3)</td> <td>538 (39.1)</td> </tr> <tr> <td>Other</td> <td>46 (7.5)</td> <td>23 (7.5)</td> <td>81 (5.9)</td> <td>82 (5.0)</td> </tr> <tr> <td>BMI, kg/m²</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Mean (SD)</td> <td>27.4 (6.3)</td> <td>27.3 (6.0)</td> <td>26.58 (6.0)</td> <td>26.85 (6.1)</td> </tr> </tbody> </table>		Study 060		Study 001			Roxa (N=616)	Placebo (N=306)	Roxa (N=1384)	Placebo (N=1377)	Race, n (%)					White	176 (28.6)	99 (32.4)	623 (45.0)	611 (44.4)	Black/African American	76 (12.3)	28 (9.2)	112 (8.1)	115 (8.4)	Asian	310 (50.3)	151 (49.3)	544 (39.3)	538 (39.1)	Other	46 (7.5)	23 (7.5)	81 (5.9)	82 (5.0)	BMI, kg/m²					Mean (SD)	27.4 (6.3)	27.3 (6.0)	26.58 (6.0)	26.85 (6.1)	<p>Table 19: NDD Studies: Demographic and Baseline Characteristics</p> <p>Study 608: Mean (SD) baseline eGFR \geq30 in Placebo arm: 27 (13.3)</p> <table border="1"> <thead> <tr> <th></th> <th colspan="2">Study 060</th> <th colspan="2">Study 001</th> </tr> <tr> <th></th> <th>Roxa (N=616)</th> <th>Placebo (N=306)</th> <th>Roxa (N=1384)</th> <th>Placebo (N=1377)</th> </tr> </thead> <tbody> <tr> <td>Race, n (%)</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>White</td> <td>176 (28.6)</td> <td>99 (32.4)</td> <td>623 (45.0)</td> <td>611 (44.4)</td> </tr> <tr> <td>Black/African American</td> <td>76 (12.3)</td> <td>28 (9.2)</td> <td>112 (8.1)</td> <td>115 (8.4)</td> </tr> <tr> <td>Asian</td> <td>310 (50.3)</td> <td>151 (49.3)</td> <td>544 (39.3)</td> <td>538 (39.1)</td> </tr> <tr> <td>Other</td> <td>54 (8.8)</td> <td>28 (9.1)</td> <td>105 (7.6)</td> <td>113 (8.2)</td> </tr> <tr> <td>BMI, kg/m²</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Mean (SD)</td> <td>27.4 (6.3)</td> <td>27.3 (6.0)</td> <td>26.68 (6.0)</td> <td>26.85 (6.1)</td> </tr> </tbody> </table>		Study 060		Study 001			Roxa (N=616)	Placebo (N=306)	Roxa (N=1384)	Placebo (N=1377)	Race, n (%)					White	176 (28.6)	99 (32.4)	623 (45.0)	611 (44.4)	Black/African American	76 (12.3)	28 (9.2)	112 (8.1)	115 (8.4)	Asian	310 (50.3)	151 (49.3)	544 (39.3)	538 (39.1)	Other	54 (8.8)	28 (9.1)	105 (7.6)	113 (8.2)	BMI, kg/m²					Mean (SD)	27.4 (6.3)	27.3 (6.0)	26.68 (6.0)	26.85 (6.1)
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