

ERRATA to FDA Briefing Document
Cardiovascular and Renal Drugs Advisory Committee Meeting
NDA 213805 (roxadustat)
July 15, 2021

Add to the list of acronyms:

DD Dialysis dependent

NDD Non-dialysis dependent

Page 23, first paragraph, line 5:

Replace this text:

For patients not on an ESA, the roxadustat starting dose was 70 mg orally thrice weekly regardless of body weight....

With this text:

For patients not on an ESA, the roxadustat starting dose was 70 mg or 100 mg orally thrice weekly depending on body weight....

Page 26, Table 13, first column:

Replace this text:

Received > courses of ESA rescue therapy

With this text:

Received > 1-2 courses of ESA rescue therapy

Page 27, Table 14, third column titled "Epoetin Alfa:"

Row "Study 063:" replace 750.3 with 951.6

Row "Study 064:" replace 951.6 with 750.3

Page 38, last paragraph, first sentence:

Replace this text:

The DD patient population includes 3880 randomized subjects who received ≥ 1 dose of study drug in the three major randomized, double-blind, active-controlled studies (002, 063, 064).

With this text:

The DD patient population includes 3880 randomized subjects who received ≥ 1 dose of study drug in the three major randomized, ~~double-blind~~ open-label, active-controlled studies (002, 063, 064).

Page 40, line three:

Replace this text:

Causes of death were not adjudicated....

With this text:

Causes of death were adjudicated....

Page 49, Figure 8, text in the lower right-hand corner, below "Hazard Ratio:"

Replace this text:

Favor ESA ->

With this text:

Favor placebo ->

Page 49, Figure 9, text in the lower right-hand corner, below "Hazard Ratio:"

Replace this text:

Favor ESA ->

With this text:

Favor placebo ->