

ERRATA SHEET TO THE CARDIOVASCULAR AND RENAL DRUGS  
ADVISORY COMMITTEE MEETING BRIEFING DOCUMENT

December 15, 2020

**Entresto<sup>®</sup>**  
**(sacubitril/valsartan)**

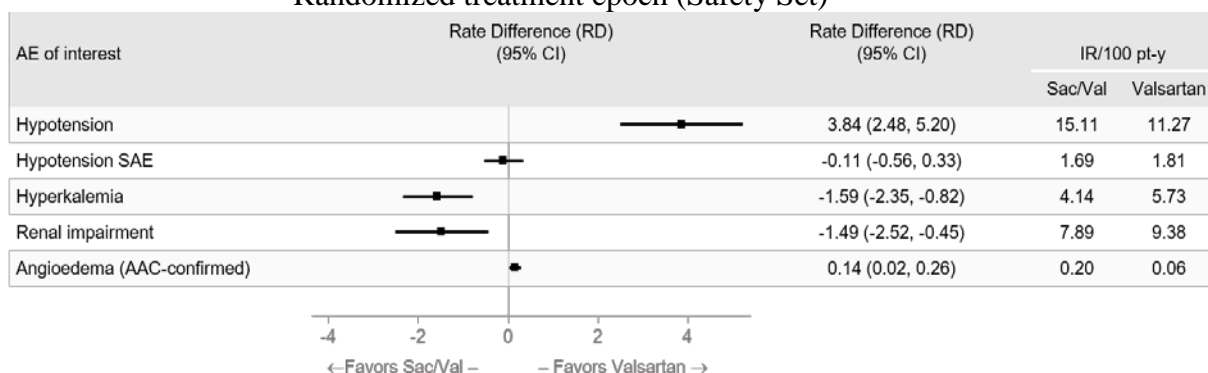
for

**Chronic Heart Failure and Preserved Ejection Fraction**

**Section 6.4.7 (Page 64) and Section 6.6.2 (Page 75)**

The 95% confidence intervals for the Rate Difference (RD) in Figure 6-11 and Figure 6-15 are corrected.

Figure 6-11 and 6-15 PARAGON-HF: Exposure adjusted incidence rate of AEs of interest in Randomized treatment epoch (Safety Set)



**Section 6.4.7.3 (Page 68)**

Table 6-25 has been updated to correctly classify the query term as Novartis MedDRA Query (NMQ). The erroneous text is identified by a strikethrough, with correction following in bold. The table footnote has been updated accordingly.

Table 6-25 Hyperkalemia in PARAGON-HF (Safety Set)

PT/Group Term	Sac/Val 200 mg BID N=2419 n (%)	Val 160 mg BID N=2402 n (%)
Hyperkalemia <del>(SMQ)</del> <b>(NMQ)</b>	272 (11.24)	363 (15.11)
Mild	172 (7.11)	210 (8.74)
Moderate	86 (3.56)	121 (5.04)
Severe	14 (0.58)	32 (1.33)
Hyperkalemia SAE <del>(SMQ)</del> <b>(NMQ)</b>	19 (0.79)	42 (1.75)
Hyperkalemia AE <del>(SMQ)</del> <b>(NMQ)</b> leading to study drug discontinuation	26 (1.07)	<del>35 (1.46)</del> <b>36 (1.50)</b>
Potassium*		
≥5.5 mmol/L	426 (17.76)	466 (19.57)
>6 mmol/L	75 (3.13)	101 (4.24)

SMQ=standard MedDRA query

**NMQ = Novartis MedDRA Query, includes PTs hyperkalemia and blood potassium increase**

\* Biochemistry laboratory results meeting specified criteria post-baseline by treatment