

ERRATA to FDA Briefing Document
Cardiovascular and Renal Drugs Advisory Committee Meeting
NDA 22034 (Vernakalant)
December 10, 2019

1. Section 13.2.6, page 35

“Table 12 shows the AESIs that occurred within 2 hours post-dose in SPECTRUM vs. the clinical studies. The incidence of these events was lower in SPECTRUM compared to clinical studies, although the numbers are small, which renders interpretation difficult. It should be noted that AEs in SPECTRUM were reported spontaneously which might have contributed to the lower frequency of these events.”

Text should read:

“Table 12 shows the **serious** AESIs that occurred within 2 hours post-dose in SPECTRUM vs. the clinical studies. The incidence of these events was lower in SPECTRUM compared to clinical studies, although the numbers are small, which renders interpretation difficult. It should be noted that **non-serious** AEs in SPECTRUM were reported spontaneously which might have contributed to the lower frequency of these events.”

2. Section 13.2.6, Table 12, page 35

The following footnote should be removed from Table 12:

“^aTwo significant hypotension events were not reported in the applicant’s AE dataset”

3. Section 14.4, Use of Cardiac Conversion Therapies, page 39

The American College of Cardiology/American Heart Association (ACC/AHA) Atrial Fibrillation Guidelines for Electrical and Pharmacological Cardioversion of Atrial Fibrillation and Atrial Flutter state ECV is preferred in patients with decompensated HF, ongoing myocardial ischemia, or hypotension.³ Electrical cardioversion is used more commonly than PCV among surveyed US cardiologists, emergency physicians, and hospitalists regarding acute management of atrial fibrillation.⁴”

Text should read:

“The American College of Cardiology/American Heart Association (ACC/AHA) Atrial Fibrillation Guidelines for Electrical and Pharmacological Cardioversion of Atrial Fibrillation and Atrial Flutter state ECV is preferred in patients with decompensated HF, ongoing myocardial ischemia, or hypotension.⁹ Electrical cardioversion is used more

commonly than PCV among surveyed US cardiologists, emergency physicians, and hospitalists regarding acute management of atrial fibrillation.¹⁰”

4. Footnote Added for References in Section 14.4, Use of Cardiac Conversion Therapies, page 39

⁹ January CT, Wann LS, Alpert JS, et al. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol* 2014;64(21):e1-76. doi: 10.1016/j.jacc.2014.03.022 [published Online First: 2014/04/02]

¹⁰ Funk AM, Kocher KE, Rohde JM, et al. Variation in practice patterns among specialties in the acute management of atrial fibrillation. *BMC cardiovascular disorders* 2015;15:21. doi: 10.1186/s12872-015-0009-1 [published Online First: 2015/04/17]

5. Remaining references should be renumbered in accordance with the two additions noted above.