

## Erratum to FDA Briefing Document

This erratum contains corrections to the FDA briefing information for the December 13, 2019, Dermatologic and Ophthalmic Drugs Advisory Committee Meeting. The corrections are minor and are not expected to impact how the committee interprets the data and/or impact the committee's discussions/vote.

1. On Page 5, the last sentence of bullet A: Efficacy:

"... ptosis ..." *should be revised to read (revision in bold and underlined): "... **proptosis** ..."*

2. On Page 34: Patient Disposition Table:

*The Patient Disposition table should be revised to read (revision in bold and underlined):*

"Patient Disposition: There were **83** subjects enrolled in the study.

	<b>Placebo (N=<b><u>42</u></b>)</b> n (%)	<b>HZN-001 (N=<b><u>41</u></b>)</b> n (%)
Enrolled (Informed Consent Signed)	<b><u>42</u></b>	<b><u>41</u></b>
ITT Population	<b><u>42</u></b> (100%)	<b><u>41</u></b> ( <b><u>100%</u></b> )
MITT Population	<b><u>42</u></b> (100%)	<b><u>40</u></b> (98%)
PP Population	<b><u>34</u></b> ( <b><u>81%</u></b> )	<b><u>33</u></b> ( <b><u>81%</u></b> )
Safety Population	<b><u>42</u></b> ( <b><u>100%</u></b> )	<b><u>41</u></b> (100%)
Completed the Study	<b><u>40</u></b> ( <b><u>95%</u></b> )	<b><u>39</u></b> ( <b><u>95%</u></b> )
Treatment Reason for Early Termination		
Adverse Event	1 (2%)	<b><u>1</u></b> ( <b><u>2%</u></b> )
Lack of Efficacy	<b><u>0</u></b>	0
Pregnancy	0	0
Protocol Violation	0	0
Study Terminated by Sponsor	0	0
Death	0	0
<b><u>Withdrawal by Subject</u></b>	<b><u>1</u></b> ( <b><u>2%</u></b> )	1 (2%)

Abbreviations: ITT = intent to treat, MITT=modified intent to treat, PP=per protocol."

3. Page 35, Review Study #2 Demographic and Baseline Characteristics (Safety Population):

- The N in the line for Weight should be changed from 44 to **42** for Placebo; and from 43 to **41** for Teprotumumab.
- The Number of Smokers should be changed from 17 (40%) to **8 (19%)** for Placebo; and from 18 (44%) to **9 (22%)** for Teprotumumab.

4. Page 42, Review Study 1:

- The header titled “Start Date/End Date” should be titled “**Day of Onset**”
  - The Day of Onset for the case of Hashimoto’s is Day 130
  - The Day of Onset for the case of Diarrhea is Day 253
  - The Day of Onset for the case of Escherichia sepsis is Day 45
  - The Day of Onset for the case of Inflammatory bowel disease is Day 169

5. Pages 42-43: The patient with back pain and back surgery in Study #1 should be moved from the Teprotumumab group **to the Placebo group**.