Protocol Amendment J2A-JE-GZPD (b)

A Phase 3, Randomized, Double-Blind Study to Investigate the Efficacy and Safety of Once-Daily Oral LY3502970 Compared with Placebo in Japanese Adult Participants with Obesity Disease (ATTAIN-J)

NCT05931380

Approval Date: 11-Jan-2024

LY3502970 Protocol J2A-JE-GZPD(b) Errata

(LY3502970 Protocol J2A-JE-GZPD(b) Approval Date: 2023/12/07)

The original text which has been removed is denoted with a ~~strikethrough~~ and the added revised text is denoted with a **<u>bold underline</u>**.

Page Section	Original Text	Correct Text	Brief Rationale
Page 4 Protocol Amendment Summary of Changes Table	8.2.6. Pregnancy Testing | Added description on at-home pregnancy testing | Clarification	~~8.2.6. Pregnancy Testing~~ | ~~Added description on at-home pregnancy testing~~ | ~~Clarification~~	This section is not amended. Therefore, this row should be removed from Protocol Amendment Summary of Changes Table.
Page 5 Protocol Amendment Summary of Changes Table		**<u>9.2 Analyses Sets</u>** | **<u>Removed full participants, updated description for randomized participants.</u>** | **<u>To follow ITT principles</u>**	This section is amended. Therefore, this row should be added to Protocol Amendment Summary of Changes Table.

<table>
<tr><th>Page
Section</th><th>Original Text</th><th>Correct Text</th><th>Brief Rationale</th></tr>
<tr>
<td>Page 27
Section.1.3,
Table 1. Period I
-Screening
Period</td>
<td>
<table>
<tr><td colspan="4">Randomization and Dosing</td></tr>
<tr><td>Urinary albumin/creatinine ratio (UACR)</td><td>X</td><td></td><td></td></tr>
<tr><td>Register visit with IWRS</td><td>X</td><td>X</td><td></td></tr>
</table>
</td>
<td>
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<tr><td><u>Urinary albumin/creatinine ratio (UACR)</u></td><td><u>X</u></td><td></td><td></td></tr>
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</table>
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<td>Urinary albumin/creatinine ratio (UACR) should be categorized under “Laboratory Tests and Sample Collections” instead of “Randomization and Dosing”.</td>
</tr>
</table>

Page Section	Original Text	Correct Text	Brief Rationale
Page 94 Section.8.2.6	On-site pregnancy testing will occur as outlined in the SoA. Female participants of childbearing potential will be supplied with home testing kits to perform additional pregnancy tests at any time during the study. Participants should notify the investigator as soon as possible if they test positive for pregnancy. Participants who become pregnant during the study should be permanently discontinued from study intervention (Section 7.1) and from the study (Section 7.2). Details of all pregnancies in female participants and, if indicated, female partners of male participants will be collected as outlined in Sections 8.3.1 and 8.3.2.	On-site pregnancy testing will occur as outlined in the SoA. ~~Female participants of childbearing potential will be supplied with home testing kits to perform additional pregnancy tests at any time during the study. Participants should notify the investigator as soon as possible if they test positive for pregnancy.~~ Participants who become pregnant during the study should be permanently discontinued from study intervention (Section 7.1) and from the study (Section 7.2). Details of all pregnancies in female participants and, if indicated, female partners of male participants will be collected as outlined in Sections 8.3.1 and 8.3.2.	Description on at-home pregnancy testing is not applicable to this study.

<table>
<tr><th>Page Section</th><th>Original Text</th><th>Correct Text</th><th>Brief Rationale</th></tr>
<tr>
<td>Page 108
Section.9.2</td>
<td>
<table>
<tr><th>Participant Analysis Set</th><th>Description</th></tr>
<tr><td>Entered participants</td><td>All participants who sign informed consent.</td></tr>
<tr><td>Randomized participants</td><td>All participants who are randomly assigned a study intervention.</td></tr>
<tr><td>Full participants</td><td>All randomized participants who meet the eligibility criteria.
Participants will be analyzed according to the treatment group to which they were randomly assigned.</td></tr>
<tr><td>Safety participants</td><td>All participants who are randomly assigned a study intervention and who take at least 1 dose of study intervention.
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</table>
</td>
<td>“Full participants” should be removed and description for “Randomized participants” should be updated.</td>
</tr>
</table>

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Approval	PPD 11-Jan-2024 08:22:46 GMT+0000

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