

Table 14-1.02
Summary of End of Study Data

| | Placebo (N=86) | Xanomeline Low Dose (N=84) | Xanomeline High Dose (N=84) | Total (N=254) | p-value [1] |
|---|-------------------|----------------------------------|-----------------------------------|------------------|-------------|
| Completion Status: | | | | | |
| Completed Week 24 | 60 (70%) | 28 (33%) | 30 (36%) | 118 (46%) | <.0001 |
| Early Termination (prior to Week 24) | 26 (30%) | 56 (67%) | 54 (64%) | 136 (54%) | |
| Missing | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | |
| Reason for Early Termination (prior to Week 24): | | | | | |
| Adverse Event | 8 (9%) | 44 (52%) | 39 (46%) | 91 (36%) | <.0001 |
| Death | 1 (1%) | 1 (1%) | 0 (0%) | 2 (1%) | |
| Lack of Efficacy [2] | 3 (3%) | 0 (0%) | 1 (1%) | 4 (2%) | 0.3281 |
| Lost to Follow-up | 1 (1%) | 0 (0%) | 0 (0%) | 1 (0%) | |
| Subject decided to withdraw | 9 (10%) | 8 (10%) | 8 (10%) | 25 (10%) | |
| Physician decided to withdraw subject | 1 (1%) | 0 (0%) | 2 (2%) | 3 (1%) | |
| Protocol criteria not met | 1 (1%) | 0 (0%) | 2 (2%) | 3 (1%) | |
| Protocol violation | 1 (1%) | 1 (1%) | 1 (1%) | 3 (1%) | |
| Sponsor decision | 1 (1%) | 2 (2%) | 1 (1%) | 4 (2%) | |
| Missing | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | |

[1] Fisher's exact test.

[2] Based on either patient/caregiver perception or physician perception.

Source: C:\cdisc_pilot\PROGRAMS\DRAFT\TFLs\adsl2.sas

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