

**Table 14.1.2**  
**Summary of Demographic and Baseline Characteristics**  
**Safety Population**

| <i>Parameter</i>  | <i>Category/Statistic</i>                 | <i>Placebo<br/>(N = 126)</i> | <i>DrugA<br/>(N = 106)</i> | <i>Overall<br/>(N = 232)</i> | <i>P-value</i> |
|-------------------|---|------------------------------|----------------------------|------------------------------|----------------|
| Age (years)       | n   | 126                          | 106                        | 232                          | 0.086          |
|                   | Mean                                      | 53.1                         | 49.7                       | 51.6                         |                |
|                   | SD  | 11.8                         | 11.7                       | 11.8                         |                |
|                   | Median                                    | 52.0                         | 50.0                       | 51.0                         |                |
|                   | Minimum                                   | 26.0                         | 19.0                       | 19.0                         |                |
|                   | Maximum                                   | 82.0                         | 76.0                       | 82.0                         |                |
| Age Group - n (%) | <65                                       | 104 (82.5%)                  | 93 (87.7%)                 |                              | 0.357          |
|                   | ≥65                                       | 22 (17.5%)                   | 13 (12.3%)                 |                              |                |
| Sex - n (%)       | Female                                    | 65 (51.6%)                   | 67 (63.2%)                 |                              | 0.084          |
|                   | Male                                      | 61 (48.4%)                   | 39 (36.8%)                 |                              |                |
| Race - n (%)      | American Indian or Alaska Native          | -                            | -                          |                              | 0.645          |
|                   | Asian                                     | 14 (11.1%)                   | 14 (13.2%)                 |                              |                |
|                   | Black                                     | 25 (19.8%)                   | 25 (23.6%)                 |                              |                |
|                   | Native Hawaiian or Other Pacific Islander | -                            | -                          |                              |                |
|                   | White                                     | 72 (57.1%)                   | 59 (55.7%)                 |                              |                |
|                   | Other                                     | 15 (11.9%)                   | 8 (7.5%)                   |                              |                |
|                   | Not Reported                              | -                            | -                          |                              |                |
|                   | Unknown                                   | -                            | -                          |                              |                |
|                   |   |                              |                            |                              |                |
| Ethnicity - n (%) | Not Reported                              | -                            | -                          |                              | 0.227          |
|                   | Unknown                                   | -                            | -                          |                              |                |
|                   | Hispanic or Latino                        | 12 (9.5%)                    | 16 (15.1%)                 |                              |                |
|                   | Not Hispanic or Latino                    | 114 (90.5%)                  | 90 (84.9%)                 |                              |                |
| Region - n (%)    | Europe                                    | 38 (30.2%)                   | 25 (23.6%)                 |                              | 0.522          |
|                   | North America                             | 66 (52.4%)                   | 61 (57.5%)                 |                              |                |
|                   | Asia Pacific                              | 22 (17.5%)                   | 20 (18.9%)                 |                              |                |
| Weight (kg)       | n   | 126                          | 106                        | 232                          | 0.635          |
|                   | Mean                                      | 74.5                         | 73.6                       | 74.1                         |                |
|                   | SD  | 15.4                         | 15.3                       | 15.3                         |                |
|                   | Median                                    | 75.2                         | 74.3                       | 74.7                         |                |
|                   | Minimum                                   | 45.2                         | 39.6                       | 39.6                         |                |
|                   | Maximum                                   | 124.5                        | 118.3                      | 124.5                        |                |
| Height (cm)       | n   | 126                          | 106                        | 232                          | 0.727          |
|                   | Mean                                      | 169.6                        | 170.1                      | 169.9                        |                |
|                   | SD  | 10.0                         | 10.7                       | 10.3                         |                |
|                   | Median                                    | 170.1                        | 170.4                      | 170.2                        |                |
|                   | Minimum                                   | 142.4                        | 146.9                      | 142.4                        |                |
|                   | Maximum                                   | 191.9                        | 197.6                      | 197.6                        |                |

Source: ADSL

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|--------------------------|---------------------------|------------------------------|----------------------------|------------------------------|----------------|
| BMI (kg/m <sup>2</sup> ) | n                         | 126                          | 106                        | 232                          | 0.713          |
|                          | Mean                      | 28.48                        | 28.08                      | 28.30                        |                |
|                          | SD                        | 5.05                         | 4.42                       | 4.77                         |                |
|                          | Median                    | 27.65                        | 28.45                      | 27.95                        |                |
|                          | Minimum                   | 16.50                        | 18.90                      | 16.50                        |                |
|                          | Maximum                   | 41.10                        | 40.40                      | 41.10                        |                |
| BMI Category - n (%)     | Underweight               | 1 (0.8%)                     |                            |                              | 0.608          |
|                          | Normal                    | 32 (25.4%)                   | 27 (25.5%)                 |                              |                |
|                          | Overweight                | 49 (38.9%)                   | 48 (45.3%)                 |                              |                |
|                          | Obese                     | 44 (34.9%)                   | 31 (29.2%)                 |                              |                |
| Smoker - n (%)           | Former                    | 55 (43.7%)                   | 30 (28.3%)                 |                              | 0.049          |
|                          | Current                   | 19 (15.1%)                   | 23 (21.7%)                 |                              |                |
|                          | Never                     | 52 (41.3%)                   | 53 (50.0%)                 |                              |                |

Source: ADSL