



Figure 1: BACLAD trial profile.

Table 1: Dose titration schedule.

| Days of Treatment | Total Daily Dose | 5 mg-Capsules | 10 mg-Capsules | 30 mg-Capsules |
|--------------------------|-------------------------|----------------------|-----------------------|-----------------------|
| Day 1 – 3 | 15 mg | 1-1-1 | - | - |
| Day 4 – 6 | 30 mg | - | 1-1-1 | - |
| Day 7 – 9 | 60 mg | - | 2-2-2 | - |
| Day 10 – 12 | 90 mg | - | - | 1-1-1 |
| Day 13 – 15 | 120 mg | - | 1-1-1 | 1-1-1 |
| Day 16 – 18 | 150 mg | - | 2-2-2 | 1-1-1 |
| Day 19 – 21 | 180 mg | - | - | 2-2-2 |
| Day 22 – 24 | 210 mg | - | 1-1-1 | 2-2-2 |
| Day 25 – 27 | 240 mg | - | 2-2-2 | 2-2-2 |
| Day 28 – 114 | 270 mg | - | - | 3-3-3 |
| Day 115 – 117 | 240 mg | - | 2-2-2 | 2-2-2 |
| Day 118 – 120 | 210 mg | - | 1-1-1 | 2-2-2 |
| Day 121 – 123 | 180 mg | - | - | 2-2-2 |
| Day 124 – 126 | 150 mg | - | 2-2-2 | 1-1-1 |
| Day 127 – 129 | 120 mg | - | 1-1-1 | 1-1-1 |
| Day 130 – 132 | 90 mg | - | - | 1-1-1 |
| Day 133 – 135 | 60 mg | - | 2-2-2 | - |
| Day 136 – 138 | 30 mg | - | 1-1-1 | - |
| Day 139 - 141 | 15 mg | 1-1-1 | - | - |