Supplemental Figure 1. Subject disposition.

- Subjects Screened (N = 921)
  - Screening Period: Up to 7 Days
  - Open-Label ITT Population (N = 667)
    - Lead-In Period: 13 weeks
    - Stabilization Period (N = 432)
    - Fixed-Dose Stabilization Period: 12 weeks
      - Randomized to Double-Blind (N = 334)

- Screen Failures (N = 254)
  - Dosing:
    - 234 mg on day 1
    - 156 mg on day 8
    - Flexible doses on days 36 (week 5 [117-234 mg]), 64 (week 9 [78-234 mg]) and 92 (week 13 [78-234 mg])

Discontinuation During Lead-In Period (N = 235)
- Adverse Event (n = 41)
- Death (n = 1)
- Lack of Efficacy (n = 26)
- Lost to Follow-Up (n = 32)
- Pregnancy (n = 1)
- Withdrawal of Consent (n = 69)
- >6 Weeks Between 2 Study Drugs (n=4)
- Subject Failed Stabilization Criteria (n = 47)
- Other (n = 14)

Discontinuation During Stabilization Period (N = 98)
- Adverse Event (n = 9)
- Death (n = 2)
- Lack of Efficacy (n = 5)
- Lost to Follow-Up (n = 10)
- Withdrawal of Consent (n = 29)
- Subject Failed Stabilization Criteria (n = 35)
- Other (n = 8)

Stabilization criteria
- PANSS total score ≤70
- YMRS and MAM-D-21 scores ≤12
The study consisted of 2 phases: 1) an open-label phase that included a 7-day screening period; a 13-week, open-label, flexible-dose, lead-in period; and a 12-week, open-label, fixed-dose, stabilization period; and 2) a 15-month, double-blind, relapse-prevention phase.

HAM-D-21, Hamilton Rating Scale for Depression, 21-item version; ITT, intent-to-treat; PANSS, Positive and Negative Syndrome Scale; PP1M, once-monthly paliperidone palmitate; YMRS, Young Mania Rating Scale

*Dose adjustments were stepwise.