BP 1
7-17 years old (n~200)

Efficacy Phase
(Subjects randomized to either placebo (PCB) or lithium (Li+) for 8 weeks of treatment)

Subjects randomized to receive Li+ (n=100)

Subjects determined to be "non-responders" (<25% reduction in baseline YMRS or CGI-I ≥ 4)

Subjects discontinued & given follow-up care

Subjects determined to be "responders" (YMRS reduction ≥ 50% & CGI-I=1 or 2) or "partial responders" (25-49% reduction in baseline YMRS & CGI-I ≤ 3)

Long-Term Effectiveness Phase
(16 or 24 weeks of open label Li+ treatment)
If patient received Li+ for 8 weeks during Study 2: 16 weeks
If patient received PCB for 8 weeks during Study 2: 24 weeks

Subjects determined to be "partial responders" (25-49% reduction in baseline YMRS & CGI-I ≤ 3) or "non-responders" (<25% reduction in baseline YMRS or CGI-I ≥ 4)

Subjects determined to be "responders" (YMRS reduction ≥ 50% & CGI-I=1 or 2)

Subjects discontinued & given follow-up care

Subjects randomized to receive PCB (n=100)

Subjects determined to be "non-responders" (<25% reduction in baseline YMRS or CGI-I ≥ 4)

Subjects discontinued & given follow-up care

Discontinuation Phase
(Subjects randomized to either PCB or Li+ for 28 weeks of treatment)

Does not meet symptom response criteria

Discontinue from study

Completes at least 6 of the last 8 consecutive weeks with complete remission of psychotic features and a remission of mood symptoms (YMRS < 10 and CDRS-R < 35)

Discontinue from study

No Mood Relapse

Complete study

Mood Relapse

Restabilization Phase
(8 weeks of open label Li+ treatment)