

Supplementary Material

Article Title: Efficacy and Safety of Iloperidone in Bipolar Mania: A Double-Blind, Placebo-Controlled Study

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Supplementary Material**Supplementary Table 1: Efficacy analysis excluding patients treated with lorazepam or benzodiazepines (mITT population)**

| Supplementary Table 1: Efficacy analysis excluding patients treated with lorazepam or benzodiazepines | | | | | |
|--|---------------|-------|-------|--------------------|---------|
| | N (ILO:PBO) | ILO | PBO | LS mean difference | P-value |
| Population | | | | | |
| mITT population | 392 (198:194) | -14.0 | -10.0 | -4.0 | <0.0001 |
| Excluding any lorazepam or other benzodiazepines | 259(137:122) | -14.1 | -10.6 | -3.4 | 0.0017 |
| Excluding any dose of lorazepam >2mg | 342(172:170) | -14.1 | -10.5 | -3.6 | 0.0002 |
| Excluding >7 doses of lorazepam >2mg | 361(184:177) | -14.0 | -10.6 | -3.4 | 0.0003 |

Supplementary Table 1: Efficacy analysis excluding patients treated with lorazepam or benzodiazepines (mITT population). LS mean change for YMRS was calculated using mixed-effects model for repeated measures (MMRM) model using the mITT population. All p-values represent iloperidone vs placebo. Abbreviations: ILO = iloperidone; PBO = placebo.

Supplementary Table 2: Efficacy subgroup analysis by presence or absence of psychotic features at baseline (mITT Population)

| Supplementary Table 2: Efficacy subgroup analysis by presence or absence of psychotic features at baseline | | | | | |
|---|-------------|-------|-------|--------------------|---------|
| | N (ILO:PBO) | ILO | PBO | LS mean difference | P-value |
| Population | | | | | |
| With Psychosis | 142 (47:57) | -15.4 | -10.5 | -4.9 | 0.0009 |
| Without Psychosis | 250 (95:97) | -13.8 | -10.2 | -3.6 | 0.0015 |

Supplementary Table 2: Subgroup analysis by psychotic features (presence or absence at baseline): change in YMRS Total Score from baseline to endpoint (Week 4). Of the 392 patients in the ITT population, 142 (36.2%) were classified as having psychotic features and 250 (63.8%) were classified as not having psychotic features at baseline. LS mean change for YMRS was calculated using mixed-effects model for repeated measures (MMRM) model using the mITT population. N (ILO:PBO) = total mITT for category (ILO:PBO mITT observed cases at Day 28). All p-values represent iloperidone vs placebo. Abbreviations: ILO = iloperidone; PBO = placebo.