



HRI 2017 Phase 3 Allergan RGH-MD-54 Outpatient Placebo-Controlled Double-Blind Bipolar I Depression Results: **Separation Between Drug and Placebo!**

HRI Enrollment Achievement

- HRI RAND 15 study participants
- With 46 US sites, HRI was 3rd highest enrolling US site (other two sites had only one subject more than HRI)
- HRI also enrolled more than any global site

Study Results

- Study showed both Cariprazine doses significantly separated from placebo, resulting in FDA approval for Bipolar I Depression in May 2019

HRI Performance Success

- While HRI's data alone could not be analyzed for statistical significance given the low n, Effect Sizes could be computed:
 - Compared to Placebo, 3.0 mg and 1.5 mg indicated Effect Sizes of 14.8 and 21 (respectively) which are relatively large
- While Sponsors consistently inform HRI of our significant active drug and placebo separation, Allergan provided HRI our unblinded data with permission to share results given our significant performance

