Conclusions

Methods

BREXANOLONE INJECTION: HUMMINGBIRD STUDIES

1. Trial 9813: 220 of 293 breastfeeding infants (BRX) enrolled at 84% (~15.4%) reduction in the BRX group compared with placebo (~29% reduction) and a National Institute of Mental Health (NIMH) report of serious adverse events. All studies used blinded follow-up. Patients received BRX 0.5 mg/kg or placebo. In three of the five trials, BRX treatment was significantly better than placebo for mean HAM-D reductions of 13 to 15. This is consistent with the findings of the Phase 3 trials in the at-risk population. The Phase 3 trials in the at-risk population were conducted in a large, well-controlled trial and showed significant improvement in the BRX group compared with placebo. The Phase 3 trials in the at-risk population were conducted in a large, well-controlled trial and showed significant improvement in the BRX group compared with placebo. The Phase 3 trials in the at-risk population were conducted in a large, well-controlled trial and showed significant improvement in the BRX group compared with placebo. The Phase 3 trials in the at-risk population were conducted in a large, well-controlled trial and showed significant improvement in the BRX group compared with placebo. The Phase 3 trials in the at-risk population were conducted in a large, well-controlled trial and showed significant improvement in the BRX group compared with placebo. The Phase 3 trials in the at-risk population were conducted in a large, well-controlled trial and showed significant improvement in the BRX group compared with placebo.