The objective of the GEMINI Phase 3 trial was to evaluate the efficacy and safety of AXS-05 compared to placebo in patients with moderate or severe MDD. The trial involved two randomized controlled trials to compare AXS-05 to bupropion, which is a well-studied antidepressant with monoaminergic mechanisms. The results showed that AXS-05 achieved the primary endpoint at Week 2 and all timepoints thereafter. AXS-05 also demonstrated statistically significantly reduced MADRS total score compared to placebo at Week 1, and statistically significantly improved depressive symptoms at Weeks 1 and 2 compared to placebo. The most common reported adverse events were nausea and headache, which were similar in overall rates across the AXS-05 conditions. In conclusion, AXS-05 is a novel oral NMDA receptor antagonist that rapidly and statistically significantly improved depressive symptoms with a favorable adverse event profile compared to placebo in the GEMINI trial.