Treatment-Resistant Depression Augmentation Therapy with An Analog of the Neuroactive Steroid Allopregnanolone: A Pilot Study

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I. BIOSTATISTICAL ANALYSIS

A. Specific data variables being collected for the study (e.g., data collection sheets)

Table 1. Schedule of Clinician and Patient Ratings

Clinician Rating	Screening	Baseline	Week 2	Week 4	Week 6	Week 8	Week 10	3 Mo Follow up
SCID and MGH ATRQ	x							
MADRS	x	x	x	x	x	x	x	
CGI-I, S		x	x	x	x	x	x	
HAM-D		x				x		
Patient Rating								
SDQ		x	x	x	x	x	x	x
IDS-SR		x	x	x	x	x	x	x
SF-36		x	x	x	x	x	x	
CHRT		x	x	x	x	x	x	
SAFTEE-SI		x	x	x	x	x	x	
CPFQ		x	x	x	x	x	x	
BFI		x	x	x	x	x	x	x
ESS		x	x	x	x	x	x	
FSS		x	x	x	x	x	x	
DISF		x	x	x	x	X	x	
SFQ		x	x	x	x	x	x	
GAD-7		x	x	x	x	x	x	x
Probabilistic Reward Task		x					x	
Pattern Separation Task		x					x	

B. Study Endpoints

The primary endpoint will be change in depression severity as measured by the change in MADRS from baseline to 8 weeks. Secondary endpoints of efficacy include both self-rated and clinician-rated assessments as listed below.

C. Statistical Methods

Data will be examined for normality using Shapiro-Wilk testing and log-transformed if not normally distributed. Longitudinal data will be analyzed using paired T tests. Univariate regression modeling will be performed to determine whether an increase in allopregnanolone levels predict an improvement in depression symptom severity.

Power Analysis

Determination of an n=10 women with treatment-resistant depression: Based on our pilot data of the effect of low-dose testosterone on depresion severity in nine women with treatment-resistant depression in which there was an effect size of 10.7 points on the MADRS with an SD 7.5, we will have ample power to detect a clinically significant effect size with the proposed sample size.[13] The data from this study will provide an effect size for power calculations for applications for further funding.