

Drug Name	GLWL-01	DCCR	Cannabidiol oral solution	Carbetocin	Livoletide
Company	GLWL Research	Soleno Therapeutics	Insys Therapeutics	Levo Therapeutics	Millendo Therapeutics
Phase¹	II	III	II	III	Phase IIb/III
Type of study²	Triple blind randomized crossover	Triple blind, placebo-controlled	Randomized, Double-Blind, Placebo-Controlled	Blinded, randomized (followed by open label)	Double blind, randomized placebo- controlled study
Route of administration	3 oral capsules twice a day	Once a day tablet	Oral solution, twice daily	Intranasal	Subcutaneous injection once per day
Eligible Ages	16-65 years old	Ages 8 and above	8-17 years of age	7-18 years old	12-65 years old
Eligible BMI³, body weight	27-60 kg/m ² ; and stable body weight for previous 3 months (no more than 10 percent change)	Not applicable	Not applicable	All BMI; no restriction	<65 kg/m ²
Eligible if living in a group home?	Yes; if 50% or less of the patients' time is spent living in a group home	May be eligible if certain other criteria are met.	Yes, but the time should not exceed 50% of the day	No	Yes, but Patients must have the same caregivers who will be able to evaluate and score the patient's behaviors and perform any study related activities as defined in the protocol throughout the study
Study Length	18 weeks	15 weeks	12 weeks	Blinded period, followed by at least 1-year open label follow up	3 months for main trial with 9 additional months in the extension period
# of doctor visits required	8	7	11	4-5 visits in blinded period, periodic visits in open label follow up	12 visits combined for the main trial and the 9-month extension period

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Primary Endpoint⁴	Hyperphagia Questionnaire for Clinical Trials (HQ-CT)	Change in hyperphagia-related behavior as measured by Hyperphagia Questionnaire (HQ-CT)	Hyperphagia Questionnaire for Clinical Trials (HQ-CT)	Hyperphagia Questionnaire for Clinical trials (HQ-CT)	Hyperphagia Questionnaire for Clinical Trials (HQ-CT)
Likelihood of being on placebo during the study?	Patients will either be on placebo first and then on active drug or vice-versa	Patients will have a 1 in 3 chance of being on placebo.	50%	Equal chance of being on placebo for blinded period	Trial is 3 arms, equally weighted with 2 active doses and 1 placebo for the first 3 months. All patients then take active drug for 9 additional months.
Can receive active drug after initial portion of the study (open label)⁵?	No	Yes, if eligible for open label extension study.	Yes	At least 1-year open label follow up planned	Yes. Patients who initially randomize to placebo will receive active drug for approximately 9 months during the open label extension.
When will trial start?	Started	Early 2018	Q2 2018	Fall 2018	Q4 2018
# of participants to be included	34	~100	60	>100	~150