A Phase 1b/2a Double Blind, Placebo Controlled Study to Evaluate the Safety, Tolerability, Pharmacodynamics, and Efficacy of CNP-103 in Participants Ages 12-35 with Recent Onsetn Stage 3 Type 1 Diabetes

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Not specified
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- 12 to 35 years old - women who are not pregnant or breastfeeding - diagnosis of Type 1 Diabetes (T1D) within 180 days prior to study enrollment - if on any medication used to treat the symptoms of T1D (e.g., corticosteroids), must be on a stable dose for at least 1 month before starting the study - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- diabetic ketoacidosis (DKA) at the time of diagnosis of T1D - see link to clinicaltrials.gov for specific criteria related to the previous use of certain drugs

Conditions & Interventions

Interventions:
Drug: CNP-103, Drug: Placebo
Conditions:
Diabetes & Endocrine
Keywords:
T1D, Type 1 Diabetes

More Information

Description: The main purpose of this study is to see how safe and tolerable CNP-103 is for people with type 1 diabetes. CNP-103 is a nanoparticle (a tiny particle) containing special beta cell proteins. In each group of adults and teens, participants will be assigned by chance (like flipping a coin) to receive either CNP-103 or placebo (like CNP-103 but contains salt water). Participants will have a 66% chance of receiving CNP-103 and a 33% chance of receiving placebo. The total duration of participation from the first Screening visit until the last assessment is approximately 208 days.
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Phase: PHASE1
IRB Number: STUDY00024994

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