Evaluate the Safety, Tolerability, Pharmacodynamics and Efficacy of CNP-106 in Subjects With Myasthenia Gravis

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 75 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Subjects who are willing and able to provide Institutional Review Board (IRB) approved written informed consent and privacy language as per national regulations. 2. Men and non-pregnant women, ages 18-75 years inclusive. 3. Female subjects of childbearing potential must agree not to become pregnant during the clinical study, have a negative pregnancy test at the Screening Visit, and agree to one of the following: * Use two highly effective forms of birth control starting at initial screening and continuing throughout the study duration. * Practice abstinence starting at initial screening and continuing throughout the study duration. 4. Subjects with a Myasthenia Gravis Foundation of America Clinical Classification Class III-IV (Cohort 1). Upon successful DMC review and approval of preliminary safety data obtained from Cohort 1 through Day 15, Cohort 2 will enroll subjects with MGFA Clinical Classification Class II-IV. 5. Subjects positive for anti-AChR antibodies by radioimmunoassay (RIA) (Mayo Clinic). 6, Subjects with MG-ADL Score ≥ 6 at Screening and Baseline Visit with ≥ 50% of the score derived from non-ocular symptoms. 7. Subjects with QMG Score ≥ 11 at Screening and Baseline Visit. 8. For subjects on any medication used to treat the symptoms of MG (ex. Corticosteroids, pyridostigmine), subjects must be on a stable dose for a minimum of 90 days prior to enrollment and must agree not to increase their dose through clinical study duration unless reviewed and approved by the medical monitor and the site investigator. 9. Female subjects who agree to not breastfeed starting at initial screening and throughout the study duration. 10. Female subjects who agree to not donate ova starting at initial screening and throughout the study duration. 11. Male subjects with a spouse or partner of childbearing potential, who themselves and their spouse or partner agree to practice an effective form of birth control as discussed with the study doctor or study staff starting at Screening and throughout the study duration.

Exclusion Criteria:

1. Subjects with a Myasthenia Gravis Foundation of America Clinical Classification Class I or V. 2. Subjects with a history of cerebrovascular accident in the past 12 months. 3. Subjects with MG-ADL Score \< 6 at Screen or Subjects with MG-ADL Score ≥ 6 at Screen with ˂ 50% of the score derived from non-ocular symptoms. 4. Subjects with QMG Score \< 11 at Screen. 5. Subjects who have used the following medications: * Tacrolimus within 6 months prior to the first dosing; * Methotrexate within 5 half-lives or 90 days after last dose (whichever is longer); * Anti-FcRn inhibitors (ex. Efgartigimod) within 5 half-lives or 90 days after last dose (whichever is longer); * C5 complement inhibitor (ex. Eculizumab) within 5 half-lives or 90 days after last dose (whichever is longer); * Anti-CD20 (ex. Rituximab) within 5 half-lives for 90 days after last dose (whichever is longer); * Inclusion of subjects on other immunomodulatory drugs will be at the discretion of the medical monitor and study site investigator. 6. Subjects who have used immunoglobulins given SC or IV (SCIg or IVIg) or plasmapheresis/plasma exchange (PE) within 4 weeks before Screening. 7. Subjects who have had thymectomy or any other thymic surgery performed within 12 months prior to Screening. 8. Subjects with untreated thymic malignancy, carcinoma, or thymoma. 9. Subjects with a history of tuberculosis or positive PPD skin test. 10. Subjects who have received administration of any live vaccine (other than intranasal Influenza) within 28 days or subunit vaccine within 14 days prior to Screening or are planning to receive any vaccination throughout the study duration. 11. Subjects who have received any COVID-19 vaccine within 14 days prior to Screening. Subjects who have received the first dose of any COVID-19 vaccine may not screen for the study until 14 days following their last dose of the vaccine if applicable. 12. Subjects with laboratory test results at Screening or prior to study dosing that are outside the normal limits and considered by the investigator to be clinically significant. Note: Clinically significant laboratory test results at screening that are related to the condition (MG) are acceptable as long as all inclusion and no other exclusion criteria are met. 13. Subjects with positive test results for hepatitis B surface antigen (HbsAg), hepatitis C virus (HCV) antibody, or human immunodeficiency virus (HIV) antigen/antibody as determined at Screening. 14. Subjects with a history of or currently active immune disorders other than MG (including autoimmune disease) unless the condition, after discussion with the medical monitor and study site investigator, has been deemed to be acceptable for the subject's participation in this clinical study. 15. Subjects with a history of or current active diseases other than myasthenia gravis requiring immunosuppressive drugs (including azathioprine, prednisone, prednisolone, budesonide, cyclosporine, tacrolimus, methotrexate, or mycophenolate mofetil) unless the condition, after discussion with the medical monitor and site investigator, has been deemed to be acceptable for the subject's participation in this clinical study. 16. Subjects with a clinical history of significant cardiovascular disease as determined by the Investigator. 17. Subjects with a complication or medical history of malignancy within the past 5 years which, in the investigator's opinion, makes the subject unsuitable for study participation. 18. Subjects with a history of mast cell activation disease. 19. Subjects who, in the investigator's opinion, will be unable to adhere to study procedures. 20. Subjects who have received an investigational therapy other than CNP-106 within 28 days or 5 half-lives, whichever is longer, prior to Screening. 21. Subjects with any known active condition which, in the investigator's opinion, makes the subject unsuitable for study participation. 22. Known sensitivity to any components of CNP-106 (PLGA, sucrose, mannitol or sodium citrate).

Conditions & Interventions

Interventions:
DRUG: CNP-106, OTHER: Placebo
Conditions:
Myasthenia Gravis, Generalized Myasthenia, AChR Myasthenia Gravis, MuSK MG

More Information

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Phase: PHASE1
IRB
Number:
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