EPPIC-Net: Novaremed Painful Diabetic Peripheral Neuropathy ISA

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

7.1 ISA-Specific Inclusion Criteria (To be used in conjunction with Platform Protocol criteria; note, some ISA criteria may be more stringent than Platform criteria; always follow the more stringent criteria when determining eligibility.) 1. Provides written consent for the EN21-01 ISA. Legally Authorized Representatives (LARs) are not allowed, but impartial witnesses may be utilized as needed for visually impaired participants. 2. Patient-reported daily 11-point NRS (for average pain over the last 24 hours) meets the criteria specified in "Appendix B: Blinded Information" during both the 7-day screening and 7-day baseline periods. The algorithm will be assessed centrally. Waivers to the inclusion criteria will not be allowed. 7.2 ISA-Specific Exclusion Criteria (To be used in conjunction with Platform Protocol criteria; note, some ISA criteria may be more stringent than Platform criteria; always follow the more stringent criteria when determining eligibility.) Participants fulfilling any of the following criteria are not eligible for the study. 1. Diagnosis of alcohol or substance abuse or dependence (other than nicotine or caffeine) within the 2 years before the Screening visit. **This criterion is more stringent than a related Platform Protocol criterion.** 2. Moderate or severe renal impairment, known (documented) or defined as an estimated/calculated creatinine clearance/estimated glomerular filtration rate (eGFR) \< 45 mL/min/1.73 m2, according to the Chronic Kidney Disease Epidemiology Collaboration formula during the screening process. **This criterion is more stringent than a related Platform Protocol criterion.** 3. Any of the following conditions related to corrected QT intervals using Fridericia's formula (QTcF): 1. A QTcF \> 500 ms prior to starting IP, up to and including the V3 pre-dose ECG. 2. A history of the following additional risk factors for torsade de pointes: heart failure, hypokalemia, history or family history of long QT syndrome. 4. History of myocardial infarction, other clinically active significant heart disease, or stroke. **This criterion is more stringent than a related Platform Protocol criterion.** 5. Participants known to have participated in four or more studies for investigational pain drugs. 6. Participants known to be non-responders to more than three previous neuropathic pain medications at adequate doses over at least 4 weeks. Adequate doses (given as total daily doses) are defined as follows: 1,800 mg gabapentin; 300 mg pregabalin; opioid analgesics 60 mg oxycodone equivalent or 200 mg tramadol; 75 mg amitriptyline or equivalent tricyclic antidepressant; 60 mg duloxetine; 150 mg venlafaxine. 7. Known hypersensitivity or contraindication to any excipients of the study drug formulation. 8. Taking prohibited medications as described in Appendix A, "Prohibited Medications." 9. Major depressive episode within the 6 months before screening and/or a history of diagnosed recurrent major depressive disorder within two years. Any of the following conditions related to suicidality: 1. Any suicidal ideation with intent, with or without a plan, at screening, i.e., answering "yes" to questions 4 or 5 on the Suicidal Ideation section of the Baseline/Screening version of the Columbia-Suicide Severity Rating Scale (C-SSRS); 2. Answering "yes" on any item of the Suicidal Behavior Section (except for the "non-suicidal self-injurious behavior") of the C-SSRS if this behavior occurred in the past 2 years; 3. A lifetime history of suicide attempt (V1). 10. Previous known or possible exposure to NRD135S.E1. Waivers to the exclusion criteria will not be allowed.

Conditions & Interventions

Interventions:

DRUG: NRD135SE.1, OTHER: Placebo

Conditions:

Painful Diabetic Neuropathy

More Information

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Principal Investigator:

Phase: PHASE2

IRB

Number:

System ID: NCT05480228