Protocol: A0081242 (LYRICA):

Study Eligibility:

Inclusion criteria:

1. Evidence of a personally signed and dated informed consent document indicating that the subject (or a legally acceptable representative) has been informed of all pertinent aspects of the study.
2. Subjects who are willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures.
3. Men or women of any race or ethnicity who are at least 18 years of age.
4. Diagnosis of type 1 or 2 diabetes mellitus with current hemoglobin A1C levels of ≤ 11% and on a stable antidiabetic medication regimen for the 30 days prior to Visit 2.
5. Diagnosis of painful, diabetic distal symmetrical sensorimotor polyneuropathy for at least 3 months; diagnosis includes absent or reduced deep tendon reflexes at both ankles (refer to Appendix 1 for diagnostic criteria).
6. Patients must be currently receiving tramadol, gabapentin, venlafaxine, duloxetine, a tricyclic antidepressant, or any combination of no more than 2 of these agents currently with inadequate pain control (as defined in Inclusion Criterion 9). Patients must not be failing this current treatment due to intolerance.
7. Patients currently receiving opioids or pregabalin for the treatment of painful Diabetic Peripheral Neuropathy are not eligible. (See also exclusion Criterion 2 for further information regarding pregabalin).
8. Patients may have no more than 2 previous treatment failures (at any time in the past) due to lack of efficacy with the following treatments: Tramadol, Gabapentin, Venlafaxine, Duloxetine, or a Tricyclic antidepressant. i.e. Not more than 3 treatment failures due to lack of efficacy total including the current treatment. Each combination of agents is considered a single treatment failure. Discontinuation of a prior treatment for painful DPN due to adverse event or due to extenuating circumstances (e.g., inability to afford to pay for continued treatment) is not considered treatment failure.
9. Patients must have inadequate pain control on the current medication(s) for painful DPN. Patients must meet the following 2 criteria demonstrating inadequate pain control while receiving treatment for painful DPN:
   a. A score of ≥40 mm on the visual analog scale (VAS) of the short-form McGill pain Questionnaire (SF-MPQ) at visit 1 and at visit 2.
   b. AND at Visit 2, subjects must have completed at least 4 daily pain diaries over the past 7 days (baseline) and have an average daily pain score of ≥ 4 (calculated by the investigative site) on the 11-point numeric rating scale.
10. Women must be nonpregnant and nonlactating, postmenopausal, or surgically sterilized, women of childbearing potential must use appropriate methods of contraception (including barrier or hormonal method); all women must have a confirmed negative serum pregnancy test at baseline.
Exclusion criteria:

1. A score of 10 on the daily pain numeric rating scale, on each of the completed baseline diaries (the 7-day interval that ends with Visit 2).
2. Have failed pregabalin treatment due to lack of efficacy, have intolerance to pregabalin or any pregabalin ingredient, or participated in a pregabalin clinical trial.
3. Have had a malignancy other than basal cell carcinoma or carcinoma in situ of the cervix within the past 5 years.
4. Have creatinine clearance (CLcr) ≤60 mL/min (estimated prior to visit 2 from serum creatinine obtained at Visit 1, body weight, age, and gender using the Cockcroft and Gault equation). Subjects who have an estimated CLcr≤60mL/min by this screening method may have their CLcr measured, at the investigator’s discretion, with a 24-hour urine collection performed at the central laboratory. If this 24-hour urine CLcr is ≤60 mL/min, the subject meets this inclusion criterion.
5. Clinically significant unstable diabetes mellitus, or unstable hepatic, respiratory, or hematologic illnesses, unstable cardiovascular disease (including a myocardial infarction in the 3 months prior to V1), or symptomatic peripheral vascular disease.
6. Abnormal (clinically significant) electrocardiogram (ECG).
7. Neurologic disorders unrelated to diabetic neuropathy that may confound the assessment of distal neuropathic pain.
8. History of pernicious anemia, untreated hypothyroidism, chronic hepatitis B within the past 3 months, or HIV infection.
9. Skin conditions in the area affected by the neuropathy that could alter sensation.
10. Other severe pain that may confound assessment or self-evaluation of the pain due to diabetic neuropathy.
11. Participation in other studies within 30 days before the current study begins and/or during study participation.
12. Prior use of potential retinotoxins such as hydroxychloroquine, deferoxamine, thioridazine, or Vigabatrin.
13. Abuse of illicit drugs or alcohol within the last 2 years.
14. Amputations of body parts other than toes.
15. Unlikely to be able to comply with the protocol because of social or other reasons; or other severe acute or chronic medical or psychiatric condition or laboratory abnormality that may increase the risk associated with study participation or investigational product administration or may interfere with the interpretation of study results and, in the judgment of the investigator, would make the subject inappropriate for entry into this study.