Title:

DPNP 214221 (NEPTUNE-"Neuropathic Pain treatment for unmet need with anti-CCL-17")

Investigators & Institutions Involved:

Investigators	Site Name/Address	Site number
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Description of Clinical Trial:

EU trial number and Full trial title

EU-CT – 2022-502313-28; A multicentre, randomised, double-blind, placebo-controlled Phase 2 study to evaluate efficacy, safety, tolerability, pharmacokinetics and target engagement of GSK3858279 in adult participants with chronic Diabetic Peripheral Neuropathic Pain (DPNP) / NEPTUNE-17.

Rationale

Diabetic peripheral neuropathic pain (DPNP) is a common long-term complication for many individuals with diabetes. Diabetic peripheral neuropathy is the damage to nerves that can cause abnormal sensations such as prickling, burning, pain or numbness, weakness in the arms, hands, legs, and/or feet. The current approved medications to treat DPNP can be associated with various side effects, making it difficult to manage DPNP effectively. There is an unmet need for new medicines to treat DPNP. It is hoped that GSK3858279 may reduce pain in individuals with diabetic peripheral neuropathy.

The purpose of the study is to collect information on the effect of the study drug on pain sensations, the safety of the study drug, and how it is processed by the body in participants with DPNP.

Objective

Primary objective

- To characterize the efficacy (how well the medicine works) of GSK3858279 on pain compared to placebo in participants with DPNP. A placebo is a dummy medicine containing saltwater solution in this study.

Secondary objectives

- To determine the safety and tolerability of GSK3858279 compared to placebo in participants with DPNP.
- To describe the pharmacokinetics of GSK3858279 (how the medicine is absorbed, modified, and removed from the body) in participants with DPNP.
- To determine and further compare the efficacy of GSK3858279 to placebo using different pain scoring questionnaires.

Main trial endpoints

- Change from baseline in average daily pain intensity will be assessed on the Numeric Rating Scale (NRS).

Secondary trial endpoints

- Occurrence of adverse events (AEs) which are medical side effects, serious AEs and AEs of special interest (AESIs).
- Key pharmacokinetic measurements including the amount of GSK3858279 over time in participants with DPNP.
- Change from baseline in pain questionnaires total score over time.

Trial Design:

This is a double-blind placebo-controlled study, where neither the participant nor the study doctor would know which treatment will be administered (GSK3858279 or Placebo). Placebo is a dummy medicine without any active substance. All participants will be divided into three groups. Two groups will receive GSK3858279 and one group will receive placebo. The two groups receiving GSK3858279 will do so at two different doses.

Inclusion Criteria/Eligibility:

Trial population

Participants with a diabetic peripheral neuropathic pain (DPNP) will be recruited in this study.

Inclusion criteria

- Men and women between 18 to 75 years of age.
- Type I or Type II diabetes suffering from painful neuropathy as a result of their diabetes.
- On a stable anti-diabetic medication regimen dose over the last 30 days prior to screening.
- A pain score ≥4 and ≤9 by the 11-point NRS for average daily pain at screening visit.

- History of insufficient pain relief from, inability to tolerate, or unable to take current standard DPNP treatment.

Exclusion criteria
Participants will be excluded from this study if these criteria apply:

- Nerve pain due to any cause other than diabetes
- History of any significant disorders including heart, kidney, liver, gastrointestinal and lymphatic diseases.

Participation Details:

Interventions

- All participants enrolled in the study will receive GSK3858279 or placebo.

Ethical considerations relating to the clinical trial including the expected benefit to the individual subject or group of patients represented by the trial subjects as well as the nature and extent of burden and risks.

- Participants may experience the benefits of pain relief and from extensive monitoring of their condition. By enrolling in this study, participants will be contributing to the development of new medicine for pain control in DPNP. The group that gets given placebo has no therapeutic effect.
- For GSK3858279 there might be a risk of allergic reactions, infections, or risks from study procedures such as blood draws. To minimise the risks to the participants, all the procedures will be done by trained clinical staff.

Funding Source: GSK

Project Start Date: September 19, 2023
Project End Date: November 13, 2024

Ethics Approval: Advarra

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