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Patient Care + Research + Clinical Trials

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NEPTUNE 17 , Clinical phase II trial, anti-CCL17 mAb in adult patients with Chronic Diabetic Peripheral Neuropathy DPNP with no relief from Standard of Care therapy

Study location BCDiabetes: 400 - 210 West Broadway, Vancouver V5Y 3W2
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Summary:
Neptune 17: is a phase II randomized controlled trial testing the efficacy, safety and tolerability of anti-CCL17 surrogate monoclonal antibodies (mAb) (GSK3858279) in adult participants with chronic Diabetic Peripheral Neuropathic Pain (DPNP**)** after they have been unable to sufficiently manage pain despite being on standard of care therapies. GSK3858279 functionally inhibits CCL17 activating the chemokine receptor CCR4, to prevent downstream consequences of CCR4 signaling.

Eligible Participants include:

- Male or female aged 18-75 years T1DM or T2DM
- Documented painful bilateral, distal lower limbs, sensory-motor neuropathy attributed to diabetes, of at least 6 months duration; Pain is not related to underlying infection, trauma or spinal disorder. Pain non responsive to current standard of care therapies
- Diagnosis confirmed by a positive Douleur Neuropathique 4 [DN4] questionnaire
- A1c < 11%
- eGFR>60
- Willing to wash off all pain relief drugs including cannabinoids, gabapentin, pregabalin, duloxetine and acetaminophen

Treatment course and duration:
A 32 weeks trial with a washout period of all DPNP medications and then randomized at 1:1:1 ratio to either GSK3858279 at 60 mg SC weekly or GSK3858279 at 360 mg SC weekly or placebo SC weekly. SC Treatment goes for 12 weeks and 15 weeks off treatment
Odds of receiving placebo ⅓ (33%)
Study documents:
Protocol Consent form Ethics Approval Ethics renewal
Conflict of Interest statement
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