ForPatients
by Roche

Type 1 Diabetes MellitusDiabetic ComplicationType 2 Diabetes Mellitus

The Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of UTTR1147A in Participants With Neuropathic Non-Healing Diabetic Foot Ulcers

Trial Status	Trial Runs In	Trial Identifier
Completed	6 Countries	NCT02833389 2015-003283-36 GX29915

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase Ib, Blinded, Randomized, Multicenter, Multiple-Ascending-Dose Study of the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of UTTR1147A Administered by Subcutaneous Injection in Patients With Non-Healing Neuropathic Diabetic Foot Ulcers

Trial Summary:

This trial will evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of repeat dosing of UTTR1147A in participants with neuropathic diabetic foot ulcers that do not respond adequately to standard wound care. Participants across multiple sites will be assigned to one of five cohorts (Cohort A, B, C, D, and E) based on the eligibility criteria and randomized to receive subcutaneous (SC) injections of either UTTR1147A or placebo over 12 weeks in addition to standard wound care.

Genentech, Inc. Sponsor	**Phase 1** Phase

NCT02833389 2015-003283-36 GX29915
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

- Have a diagnosis of Type 1 or Type 2 diabetes and confirmed peripheral neuropathy
- Have adequate circulation to the foot
- Have an ulcer area at screening up to 6 cm^2
- Up to date on all age-appropriate cancer screenings per local standards

Exclusion Criteria:

- Have current evidence of osteomyelitis, cellulitis, or evidence of systemic infection
- Have gangrene present on any part of the affected foot
- Known peripheral arterial disease requiring revascularization
- Have a glycated hemoglobin A1C level of greater than (>) 15% assessed at screening
- Are receiving oral or parenteral corticosteroids, immunosuppressive, or cytotoxic agents
- Have active malignancy or any history of a malignancy
- Use of oral antibiotics at the time of randomization for any reason in participants to be enrolled in Cohorts A, B, E, and any additional uninfected patient cohorts