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**Principal Investigator** Michael Rickels

**Study Title:** A phase 3, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of 400 mg twice a day oral ladarixin in patients with new-onset type 1 diabetes and a low residual  $\beta$ -cell function at baseline

**Purpose:**

The main purpose of the study is to check if the study drug, ladarixin, is safe and if it is effective in preserving the function of beta cells in the pancreas. This study aims to assess whether ladarixin study treatment is capable of slowing down the progression of type 1 diabetes.

**Brief Description**

This study is designed for adults with newly diagnosed with Type 1 Diabetes who are taking their first dose insulin within 100 days.

If you agree to take part in this study, you will receive ladarixin or placebo (oral capsules that look the same as the study drug but do not contain any active ingredients) at a dose of 400 mg twice a day. In each study treatment cycle (4 weeks, around 1 month), you will have to take ladarixin or placebo for 14 days alternated with 14-day breaks, where you do not take ladarixin or placebo.

**Eligibility**

Male and female patients aged 14-45 years, inclusive;

New-onset T1D (1st IMP dose within 100 days from 1st insulin administration);

Require, or has required at some time, insulin therapy through multiple daily injections (MDI) or Continuous Subcutaneous Insulin Infusion (CSII).

Patient able to comply with all protocol procedures for the duration of the study, including scheduled follow-up visits and examinations;

Patients who have given written informed consent prior of any study-related procedure not part of standard medical care (participants under the age of 18, shall provide an assent for the study as per country requirements). Specific consent must be given by adolescents to be selected for the full PK analysis.

**Compensation (if applicable)**

Subject will be paid \$75 for each completed study visit.

**Which section would you like the trial listed under?** Rodebugh Center Trials

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