Identifiers: NCT04190693

Title: IMCY-T1D-002: Long-term Follow-up Study of T1D Patients Previously Treated With IMCY-0098 or Placebo

Date : 23 Dec 2021

Study Protocol

Design: This was a non-therapeutic, double-blind, placebo-controlled multi-center, long term follow-up (LTFU) study of patients who received IMCY-0098 or placebo in the main study (IMCY-T1D-001).

Ethics: The clinical study protocol (CSP, EudraCT number: 2018-003728-35) and information provided to patients and any recruitment advertisements were reviewed by an independent ethics committee (IEC), in accordance with regional requirements. All participants provided written informed consent. The protocol was publicly registered through Clinical Trials (NCT04190693).

Dates: The study was conducted from 2019-02-14 (date of first patient Visit 1) to 2019 10 08 (date of last patient last visit)

Subjects: All patients who were treated with IMCY-0098 or placebo in the main study and were willing to participate in this LTFU study, were included

Objectives:

The primary objective of this study was to assess the long-term safety up to 48 weeks after the randomization in the main study.

The secondary objective of this study was to evaluate the clinical response to IMCY-0098 by assessing disease activity.

Statistical Analysis Plan

There is no definition of the sample size specifically for this LTFU study. The maximum number of patients who will participate is the number of patients who were enrolled in the IMCY-T1D-001 study.

The analysis was performed when all patients have completed last visit.

All primary, secondary and exploratory endpoints were summarized by descriptive statistics (continuous variables) or frequency tables (categorical variables), by dose group and overall.