IMCY-0098 belongs to a new class of active and specific immunotherapies (Imotopes™) for the treatment of severe chronic autoimmune diseases.

It has been tested previously in a first clinical study on 31 patients and demonstrated a safe profile.

Healthy situation
Immune system « harmony »

Type 1 diabetes state
Immune system « dysregulation »

IMCY-0098 treatment
New protective immune cell

This study will test this new promising drug for the treatment of type 1 diabetes within the INNODIA European platform.

Objectives of IMPACT study

• Determine the optimal dose and number of injections
• Evaluate the clinical efficacy of IMCY-0098
• Confirm its safety in young adults and adolescents
• Detect and describe the new immune cells induced by the treatment
Conditions of participation

• Age ≥18 and <45 years at consent
• Diagnosis of T1D within 9 weeks at screening (date of 1st insulin injection)
• Being on insulin treatment
• Having at least one diabetes-related autoantibody present at screening
• Having random C-peptide levels ≥200 pmol/L measured at screening
• Being HLA DR4 positive

Study visits and main assessments

Study program outline

• 6 treatment visits and 3 follow-up visits
• 2 injections of IMCY-0098 at each treatment visit
• Total study participation will last approximately 1 year including screening

Next to the classical assessments to evaluate your health (vital signs, physical examination, side effects, ...), the following specific tests will be performed:

• Mixed Meal Tolerance Test (MMTT)
• Numerous blood samples for immune analysis
• Follow-up of potential injection site reactions
• Dry Blood Spot (DBS) at home