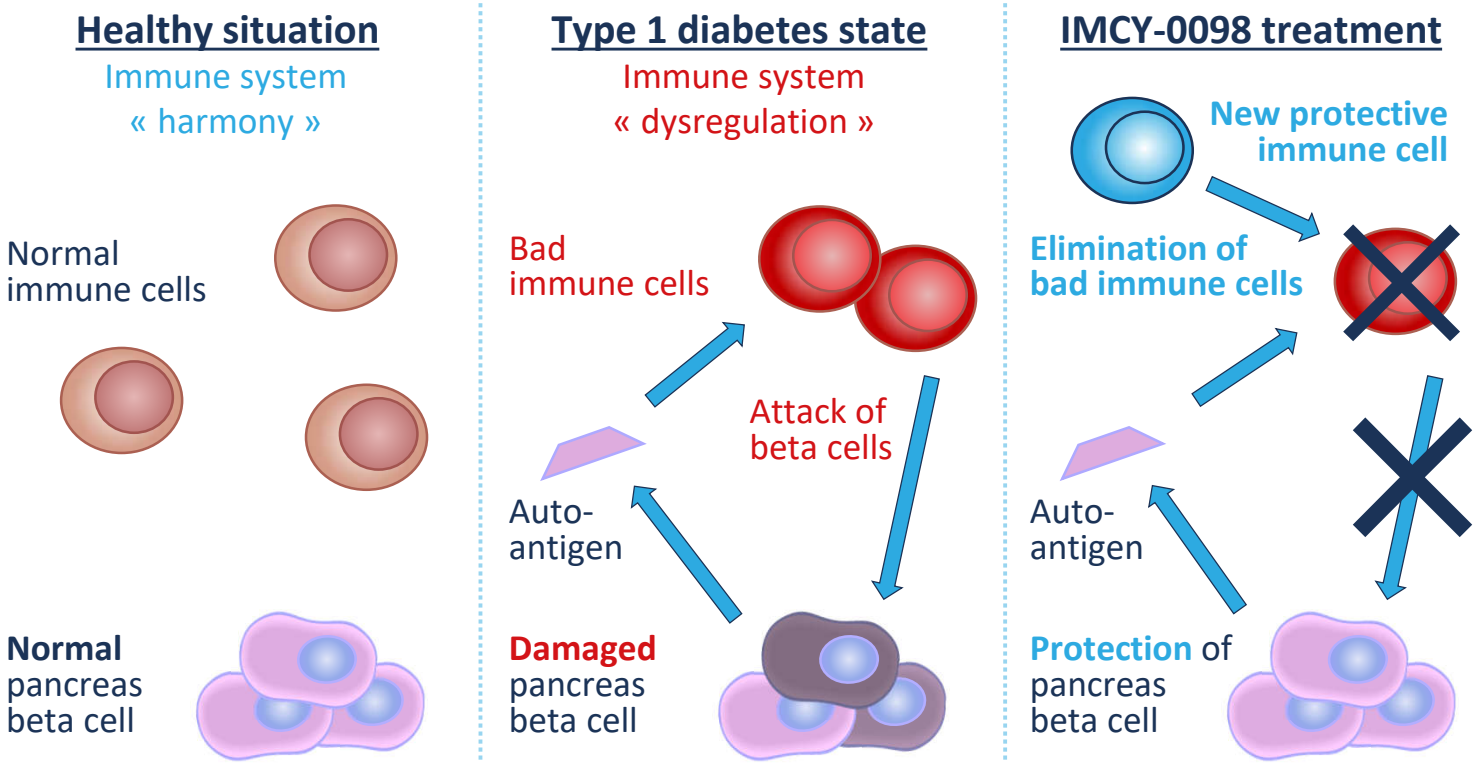
Impact

by Imcyse in collaboration with INNODIA

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.**



This study will **test this new drug** for the **treatment of type 1 diabetes** in collaboration with the INNODIA European platform.

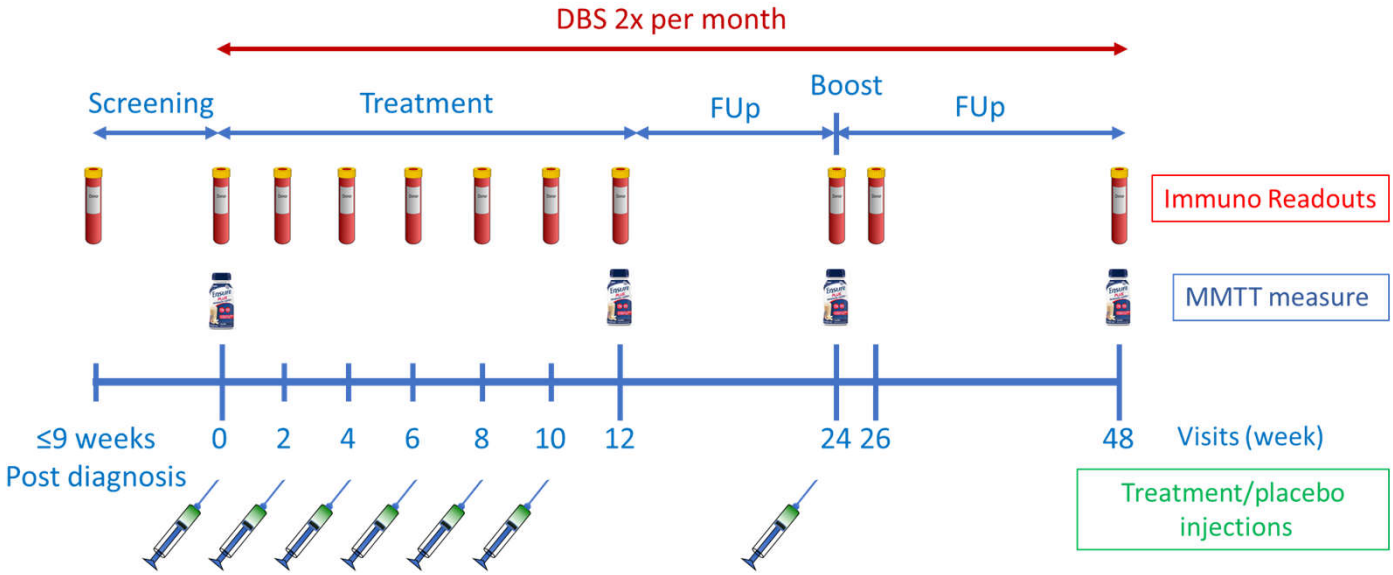
Objectives of IMPACT study

- Determine the **optimal treatment dose**
- Evaluate the **clinical efficacy** of IMCY-0098
- Confirm its **safety** in adults
- 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**
  - Up to 24 DR4 negative (but DR3 positive) patients will be able to participate in a substudy

Study visits and main assessments



Study program outline

- **7 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