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Long-term follow-up study of T1D patients previously treated with IMCY-0098 or placebo in young adults with recent-onset type 1 diabetes

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Abstract:
Background and aims: Type 1 diabetes (T1D) is an auto immune disease for which no curative treatment currently exists. IMCY-0098 (human T1D-peptide) is an innovative immunotherapeutic technology consisting of a synthetic peptide containing an MHC class II epitope of proinsulin linked to a thioredox motif. It is an antigen-specific therapy leading to the generation of cytolytic memory CD4 T cells targeting the pathogenic auto-immune response whilst preserving overall immune competence of diabetic patients. The safety, clinical efficiency and immune responses induced by IMCY-0098 treatment were evaluated in the IMCY-T1D-001, a phase 1b double-blind, placebo-controlled, multi-centre study in young adults with recent-onset T1D. Herein, we present the results of a long-term follow-up (LTFU) study on these patients.
Materials and methods: This study involved a follow-up of 6 months after the end of the initial participation. At week 24 of the IMCY-T1D-001 study, patients were offered to participate to this LTFU study including additional assessments at week 36 and week 48 after the first administration of IMCY-0098. Mixed meal tolerance tests (MMTT) were performed at week 36 and week 48 and the daily doses of insulin treatment were recorded. PBMCs were also collected at week 48 to measure IMCY-0098 specific cytolytic CD4 response and beta-cells antigen specific effector T cell responses by flow cytometry. Data were analysed using a datamining approach with artificial intelligence-based Knowledge Extraction and Management (KEM) technology.
Results: 30 out of 41 patients were re-consented. All received 4 injections of IMCY-0098 or placebo during the main study. 11 patients refused participation or were lost to follow-up. Overall, the study provided evidence of long term (up to 48 weeks) safety and tolerability of the study drug. The safety analysis identified 24 TEAEs that were mild or moderate in intensity and not related to IMCY-0098, except for 1 event of hypoglycaemia that was judged as possibly related and resolved by the end of the study. The positive early clinical and immunological trends observed in the main study up to 6 months, were not confirmed at 48 weeks after start of the treatment or were less prominent. However, due to the low number of observations and in-group variability, the study was explorative and was not designed or powered to demonstrate efficacy.
Conclusion: Results of this LTFU clinical trial have confirmed the excellent safety profile of IMCY-0098 observed in the IMCY-T1D-001 study, reaching the primary study objective. The positive trend in clinical and immunological parameters improvement detected in the main study was not observed in the LTFU. The current data suggest that the right dosage or regimen (number and timing of injections

of IMCY-0098) to elicit a significant and long-term effect is yet to be identified. Overall, the results of the main study and the LTFU are very encouraging and informative. Further exploration is needed in a next clinical trial already in preparation under the master protocol and the support of the European Consortium INNODIA.

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