

## Development of therapeutic drug for type 1 diabetes

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Autoimmune diseases are classified into two types; Th1 type and Th2 type in both of which Th1/Th2 balance is skewed to either side. We aimed to normalize the skewed Th1/Th2 balance in type 1 diabetes, one of Th1 type autoimmune diseases. Some foreign protein derived from living organism with a code number KVT-1 was injected along with adjuvant to NOD mice, a murine model for type 1 diabetes, at 4 weeks of age. We successfully inhibited lymphocyte infiltration in and around pancreatic islets in NOD mice after administration of KVT-1. Even single dose of KVT-1 worked with adjuvant.

The target mechanism of current marketed immunomodulatory drugs is to deplete T lymphocytes in inflammation lesions or to suppress inflammatory cytokines. These drugs may cause infectious diseases. KVT-1, however, does not pose such concern, because KVT-1 is intended to simply normalize the immune system from the skewed Th1/Th2 balance in type 1 diabetes.

KVT-1 is a group of large molecule foreign antigens to humans as well as to mice. Allergic responses may be generated in clinical setting. KVT-1 would be formulated with adjuvant not to enhance immunological reactions but to sustain gradual release of KVT-1 from the local injection site, which should prevent anaphylaxis in the patients. No IgE class antibody against KVT-1 was detected in NOD mice after single dose along with adjuvant.

KVT-1 can be a curative medicine for type 1 diabetes which is unmet need of the therapy. Although the anaphylaxis risk is considered to be minimum if KVT-1 is administered once along with adjuvant, it is preferable to identify the most effective part (epitope) of KVT-1 and to downsize its body. In addition, the combination therapy with another class of drug


is expected to be more effective.



### Speaker Biography

Kazuichi Nakamura has experience in working for a pharmaceutical company for about 25 years. His specialization area is immunotoxicology. He started his current career in researching and teaching in the veterinary school, 2014. Since then, he has been being enthusiastic to develop therapeutic drugs for autoimmune diseases based on his experience in drug development and his knowledge in immunology. KVT-1 is one of the results of his research over the past 5 years in Kitasato University. He does not think that immunoenhancement cause autoimmune diseases. Immunoenhancement is a consequence of autoimmune diseases. Therefore he did not take immunosuppressive approaches, but tried to modulate the immunological condition behind the disease. As he believes combination therapy is more effective for remission of type 1 diabetes, he is now seeking for several opportunities of collaboration. The final goal of his research is obviously to improve the patients' quality of life.

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