

Technology Available for License Novel Agents to Enhance Tolerance to an Immunogen

Acquired immunologic protection against foreign antigens often requires the administration of varying, and often unknown, amounts of antigen to create the desired protective mechanisms. Successful achievement of immunologic protection also depends upon systemic unresponsiveness to the foreign antigen as it is being administered during the adaptation phase. Though the precise mechanisms by which delivery of antigen elicits a state of systemic unresponsiveness are not fully understood, the dosage of antigen has been shown to be an important factor.

From the laboratory of Dr. David Pascual, a new approach to developing highly potent, antigen-specific agents, called “tolerizing agents”, uses a mucosal targeting ligand fused to a specific antigen to induce host unresponsiveness solely to that antigen while avoiding global immune suppression. The ligand protein can be fused to a broad range of antigens enabling tolerance to a number of autoimmune diseases, inflammatory diseases, other allergens and biologic therapeutic molecules (e.g., botulinum toxin). Furthermore, the addition of a tolerizing agent mediates tolerance after a single oral dose or with minimal dosing; eliminating the problem of conventional tolerization regimens that require high doses or repeated dosing of antigen. In addition, studies have shown that the fusion protein is capable of regulating peripheral tolerance to either nasal or oral delivery providing convenience for the patient and increased patient compliance. Finally, in a mouse model of multiple sclerosis following immunization using the tolerizing agent, animals treated at the peak of disease showed reversal of neurological dysfunction in less than 24 hours, suggesting high clinical efficacy of these agents.

Benefits:

- Tolerance can be obtained, in some cases, with as few as one dose
- Induction of antigen-specific tolerance avoiding global immune suppression
- Convenience of either oral or nasal delivery
- Range of antigens can be fused to mucosal ligand delivery molecule to develop different and highly selective “tolerogens” to specific diseases
- Rapid disease reversal with significant clinical efficacy

Current Status of the Technology:

A U.S. patent #7,910,113 has issued on this technology and further research is ongoing with publications available upon request.

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