November 28, 2023 **BOME Pharma LLC** tel 856.759.1299
www.BOMEpharma.com *World's first safe & effective allergy vaccine for Poison Oak & Ivy*. fax 856.759.1288
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What is VDBP?

Until we discovered Vaccine Delivery by Precipitation (VDBP), medications were injected into solid body tissues in only two ways. Meds that are soluble in water, including most US-licensed allergy vaccines, could be injected as solutions. Meds injected as solutions spread very quickly from the injection site as individual molecules. Or, they can be formulated as complexes that are not soluble in water. These are injected as blobs that mostly remain where they are injected and dissolve slowly. They also release meds as individual molecules but more slowly and over longer periods of time.

Meds that are not soluble in water can sometimes be formulated into water-soluble complexes that behave much like water-soluble drugs. They can also be injected as blobs that slowly release drug also molecule by molecule.

For VDBP a drug or vaccine must be insoluble in water but a therapeutic dose must be soluble in a medically safe small volume of a solvent that mixes freely with water. Ethanol, acetonitrile and dimethylsulfoxide are the three water-miscible solvents that are medically safe for delivery to many body tissues if given in small enough amounts. The volume of solvent in which the dose is dissolved must also be small enough to be rapidly diluted by the water content of the target tissue. Speed of dilution is important because as the solvent is diluted the dissolved drug or vaccine becomes insoluble and precipitates. The more rapid the dilution, the larger the number and smaller the size of the particles into which it precipitates. Depending on the substance, the resulting particles may be either solid of small globules of liquid drug or vaccine. Particles in the size range from 0.5 to 5 microns in diameter are efficiently taken up and carried to the structures within lymph nodes where immune response switching takes place, by the wandering antigen-presenting cells that perform continuous immunological surveillance of all body tissues except the eyes, spine and brain, If an injection of 0.15ml of a vaccine containing 100 mg of urushiol per ml is diluted at a rate to deliver a median particle size in the middle of this range, 2.6 microns in diameter, it will populate the volume around the injection site with 200 million such particles. What we discovered and patented is the only known way to suddenly populate a solid tissue of a living human or animal with tens to hundreds of millions of bite-sized particles of vaccine to feed the cells that present those antigens for immunomodulation.

The potency of this method of vaccine delivery to the immune system is demonstrated by its first-in-the-world successful induction of tolerance in persons already allergic to poison ivy. This goal eluded dozens of investigators whose unsuccessful efforts with other methods of vaccine delivery are published in more than 100 medical journal articles spanning more than 100 years.

We believe the effectiveness of this method of feeding antigen to the immune system can be exploited for other targets of therapeutic immunomodulation, as well. These include better vaccines for allergies to foods and insect stings, other materials causing allergic contact dermatitis, allergies to latex, to surgical implants and possibly to prevent rejection in tissue and organ transplantation.

The mechanism of immune response switching between sensitization and tolerance is the same in both directions. With different choices of target tissue and other measures to bias the system

toward one direction or the other we believe VDBP can be used to achieve immunomodulation from tolerance to protective sensitization in cancer, and from naivete to protective sensitization in infectious diseases for which other modalities of vaccine delivery have been ineffective or suboptimal, including malaria, tuberculosis, Zika, Ebola and Sars CoV-2.