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Mapping the Selection and Development of Adjuvants for Vaccines

Sudha Chivukula, PhD; Head Virology Research N.A Sanofi Pasteur

Vaccines have played a significant role in controlling and preventing infectious diseases. Vaccines have saved 730,000 lives and prevented 21 million hospitalizations in the United States from 1994 to 2013. Adjuvants are important components of vaccines that cause localized activation of innate immune system promoting antigen-specific adaptive immunity. Last couple of decades has witnessed approval of few vaccines formulated with new generation of adjuvants targeting diseases such as hepatitis B, cervical cancer, influenza, shingles and malaria. Rationale to include an adjuvant and the choice of the adjuvant needs comprehensive evaluation of immune biology and pathogenesis as well as generation of comprehensive data package for the safety, tolerability and efficacy of the adjuvant. A framework for a novel adjuvant development pathway will be dissected using Sanofi Pasteur's AF03, an oil-in-water emulsion adjuvant as a model. The outcomes of preclinical, CMC and clinical studies for AF03 have established AF03 as a safe, potent and industrially viable adjuvant. Preclinical studies showed the adjuvant enhances Hemagglutinin antibody (HAI) response against pandemic Influenza strains. In clinical studies, AF03 adjuvanted A/California/7/2009(H1N1) pandemic influenza vaccines were safe and did not show any unexpected trends in adverse events. Inclusion of adjuvant in the vaccine resulted in increased HAI titers, especially in very young, a dose sparing effect as well as an increase in the duration of circulating HA antibody.