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Development of the intranasal RSV vaccine SynGEM

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Respiratory syncytial virus (RSV) is an important cause of respiratory tract disease in (naive) young infants, older infants, the elderly and immune-compromised. Despite the medical need and the market potential, no licensed vaccine is available. Each of the target populations differs fundamentally with respect to its immune-capabilities and RSV history. It is therefore the current understanding that different populations present different challenges for vaccine development. An intramuscular vaccine that elicits high VN titers is now considered the most suitable approach for maternal vaccination of pregnant mothers. The placental transfer of antibodies to the foetus should protect the naive infant up to the 6 month of live. On the other hand, a mucosal vaccine that inactivates the virus in the upper respiratory tract (already at the port of entry) may be attractive for vaccination of other target groups like children older than 6 months as part of a cocooning strategy to protect vulnerable people (elderly, immune-compromised and naives). In support of the mucosal approach, there is accumulating evidence that F-specific local S-IgA antibodies secreted in the upper respiratory tract of humans, correlate well with protection. Because of its ability to induce broadly neutralizing antibodies the RSV F protein is the most attractive antigen. The current view is that in particular serum antibodies directed against the prefusion form of RSV F belong to the most potent neutralizing antibodies and the ability to elicit these is a pivotal attribute for a successful RSV vaccine. We studied different variants of F with respect to their conformation using neutralizing monoclonal antibodies, following the view that F proteins mimicking the meta-stable prefusion form of F expose a more extensive and relevant epitope repertoire than F proteins corresponding to the postfusion F structure. Both addition of a trimerization motif and mutation of the furin cleavage sites increased the reactivity of F with the prefusion-specific D25, with the highest reactivity being observed for F proteins in which both these features were combined. The RSV vaccine SynGEM based on this prefusion-type F protein was evaluated in several animal models and is currently in development for clinical trials. Our progress in these areas will be discussed.

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Optimization of up-streaming production process of acellular pertussis vaccine

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Acellular pertussis vaccine requires fermentation, isolation and purification of antigenic components i.e. pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (69kD protein), fimbrie 2 and 3. The number of doses per fermentation batch of acellular pertussis vaccine is usually 20-25 times lower than whole cell pertussis vaccine. It is necessary to increase the titre of antigenic components and final yield during process of acellular pertussis vaccine. This study includes selecting the high titre strain of *B. pertussis*, optimization of growth medium and cultivation condition for maximum production of these antigens. An increase in the productivity by employing fed – batch rather than the currently used batch cultivation of *B. pertussis* could reduce the cost of acellular pertussis vaccine.

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