Preclinical Evaluation of a Novel Epicutaneous Vaccine against Respiratory Syncytial Virus*

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In order to be able to put an RSV vaccine onto the market, new vaccination strategies combining scientific and technical innovation need to be explored. In the present project, we describe the development and the non-clinical evaluation of an original epicutaneous RSV vaccine that combines two patented technologies: Viaskin® epicutaneous patches developed by DBV Technologies as a delivery platform, and RSV N-nanorings fused to the F epitope targeted by palivizumab (N-FsII) developed by the French National Institute for Agronomical Research (INRA) as a subunit antigen. We have demonstrated that Viaskin® loaded with a formulation containing N-FsII antigen (Viaskin®-N-FsII) is highly immunogenic in mice and promote a Th1/Th17 oriented immune response. More importantly, Viaskin®-N-FsII epicutaneous vaccine confers a high level of protection against viral replication upon RSV challenge in mice, without exacerbating clinical symptoms. In swine, which provides the best experimental model for the cutaneous passage of drug/antigen in human skin, we have demonstrated that Viaskin®-N-FsII induced a significant RSV N-specific T-cell response. Using this animal model, we have also shown that GFP fluorescent N-nanorings, delivered epicutaneously with Viaskin® patches, are taken up by epidermal Langerhans cells. In conclusion, Viaskin®-N-FsII epicutaneous vaccine seems efficient to protect against RSV infection in animal model. Moreover, since no injection is required and no skin conditioning is needed before application of patches, Viaskin®-N-FsII epicutaneous vaccine would provide a pertinent and safe solution for the vaccination of newborns.

**Abstract presentation at the RSV Vaccines for the World 2015 (RSVVW) Meeting, 18-20 November 2015 – California (USA)*