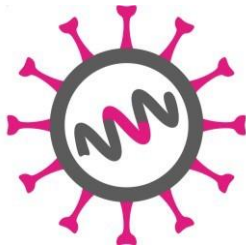




## Technology Offer



**vir4vac**

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## A novel platform for mucosally-applied vaccines that induce sterilizing immunity against respiratory viruses

File no.: 0204-3324-IKF; 0204-6368-IKF

### Background

All vaccines licensed for adults against respiratory viruses still must be applied intramuscularly (i.m.); accordingly, they do not induce mucosal immunity and thus are not able to interrupt viral transmissions; this especially is true for the main winter season pathogens such as SARS-CoV-2, RSV and influenza virus. Therefore, there is a high medical need to develop vaccines which specifically can be applied via mucosal routes of virus infections (such as the hallmark oral poliomyelitis virus vaccine that became a game changer in the 1950<sup>ies</sup> by ablating all intestinal polio transmissions).

### Technology

In response to this, scientists from Max-Planck-Institute of Biochemistry, Martinsried, have generated a novel nasal-applicable “vir4vac” vaccine platform which is fully functional against major highly pathogenic respiratory viruses.

As its backbone this “vir4vac” platform employs a well-characterized non-pathogenic respiratory virus (Sendai virus (SeV)), which is highly flexible to encode and insert surface proteins of pathogenic respiratory viruses into its envelope. Thus, “vir4vac” vaccines can completely mimic infections with these pathogenic respiratory viruses. They also guarantee the prevention of (i) uncontrolled vaccine spread, (ii) vaccine shedding, (iii) vaccine persistence and (iv) potential mutations/conversion of “vir4vac” vaccines within vaccinated people, making those vaccines even suitable for (high-) risk groups like immuno-compromised patients, young children and the elderly. Another important feature is the non-traumatic intranasal (i.n.) administration (NO needles are required!).

Beyond that, absence of any pre-existing anti-(SeV) vector immunity or pre-immunity in humans allows (i) protection directly in the airways reached by induction of a **profound anti-viral mucosal immunity, a prerequisite for STERILIZING IMMUNITY**, followed by a (ii) strong humoral and cellular immunity (i.e., induction of specific B- and T-cell responses). Furthermore, the attenuation of all “vir4vac” vaccine candidates can be easily regulated from fully replication-deficient, thus characterized by excellent safety features<sup>2,3</sup>, to fully replication-competent.

### The vir4vac project

Proof of concept (PoC) of the **vir4vac vaccine platform** has been demonstrated already preclinically with a vaccine candidate encoding the F surface protein of Respiratory Syncytial Virus (RSV). Efficient mucosal as well as systemic antibody responses and **protection against challenge infections** have been demonstrated<sup>3</sup> (see Fig. 1, next page). **This vir4vac RSV vaccine candidate is now ready for clinical development.** Furthermore, also our candidate for vaccination against SARS-CoV-2 already is in advanced preclinical characterization.

Thus, **our novel first-in-class intranasally applicable, recombinant RNA-vectored vir4vac vaccines** constitute a safe and very efficacious way of preventing serious respiratory infections **by completely blocking transmission** of highly pathogenic viral agents. This guarantees exclusivity when comparing our approach with any of our competitors.

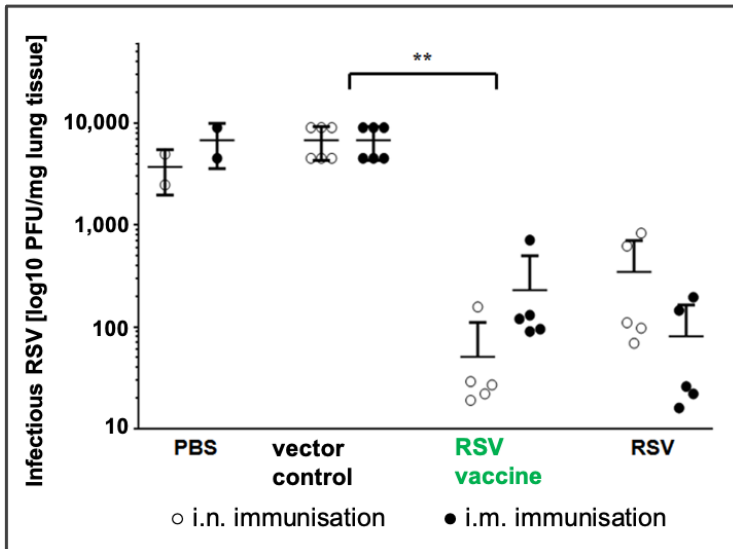


Figure 1. Protection against virus challenge after mucosal vaccination of BALB/c mice with two doses of one of our **vir4vac** vaccine prototypes (here for vaccination against RSV<sup>3</sup>; i.n.: intranasal immunization; i.m.: intramuscular immunization)

## Opportunity

Current funding was covered academically (EU grants and others). We are now looking for either an **investor** and/or a **licensing partner** for our **vir4vac** technology who is interested in the further clinical development of our state-of-the-art RNA-vectored vaccine platform (firstly covering the costs for CMC and a Phase I trial).

## Patent Information

- **Initial basic patent** (PCT/EP2006/001251) covers the **vir4vac** technology very broadly. It was granted in **US, Europe and China**.
- **New International Patent Application** No. PCT/EP2023/064144, was filed on **May 25, 2023**.
- According to our patent strategy, **further filings are currently in preparation**.

## Selected Publications

1. Wiegand M, Neubert WJ. Sendai Virus Vector: Advantages and Applications. Genome replication-incompetent Sendai virus vaccine vector against respiratory viral infections (Chapter 4: 91-126). Y Nagai (ed.), *Springer Japan 2013*. ISBN 978-4-431-54556-9 (eBook).
2. Wiegand M, Gori-Savellini G, Martorelli B, Bossow S, Neubert WJ, Cusi MG. Evaluation of a novel immunogenic vaccine platform based on a genome replication-deficient Sendai vector. *Vaccine* 2013; 31(37):3888-93.
3. Wiegand MA, Gori-Savellini G, Gandolfo C, Papa G, Kaufmann C, Felder E, Ginori A, Disanto MG, Spina D, Cusi MG. Respiratory syncytial virus (RSV) vaccine vectored by a stable chimeric and replication-deficient Sendai virus protects mice without inducing enhanced disease. *J Virol* 2017; Apr 28;91(10).