vir4vac

Technology Offer

A new VACCINE type able to induce sterilizing immunity against epidemic threats caused by viruses such as SARS-CoV-2 (COVID-19) or other respiratory pathogens

Ref.-No.: 0402-3324-IKF

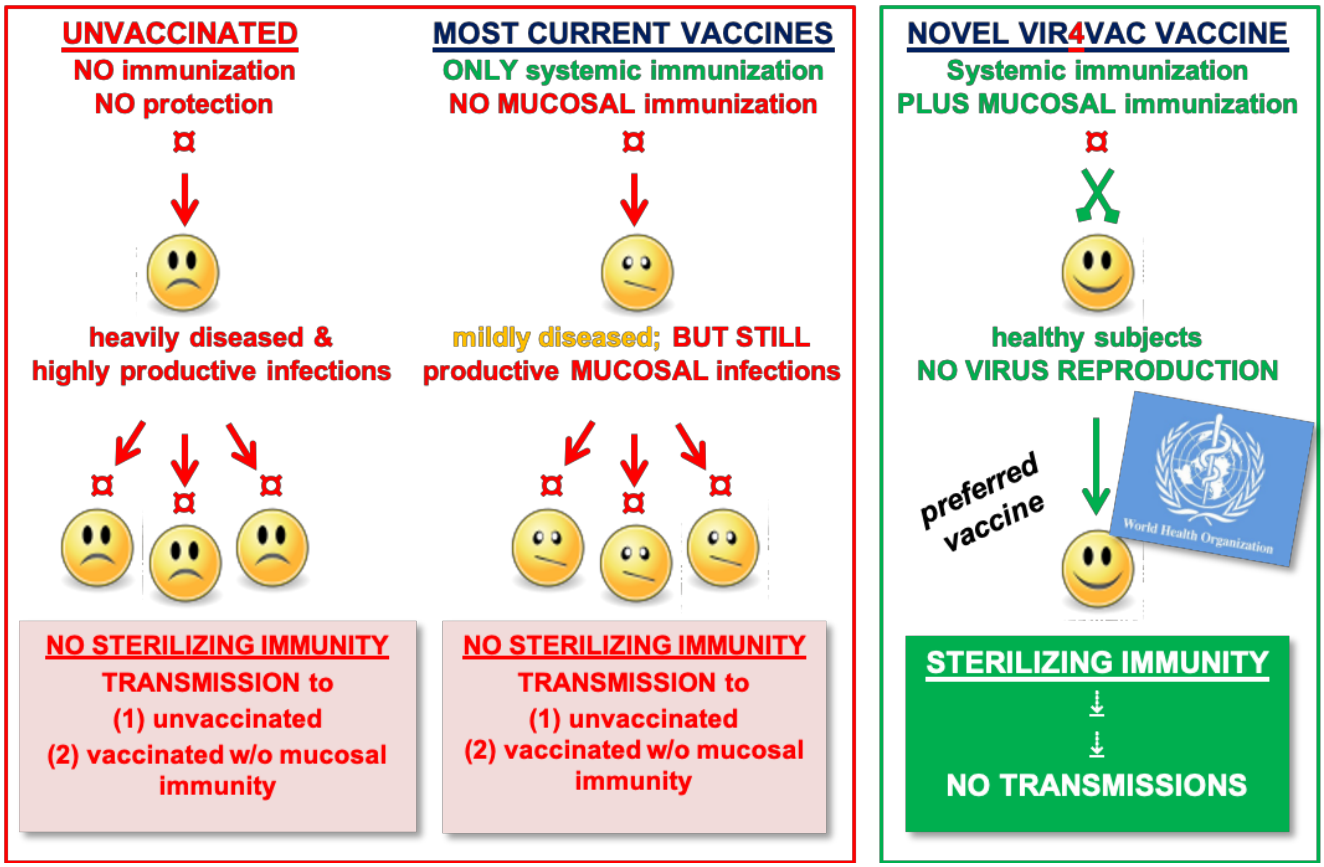
"Novel first-in-class intra-nasally applicable safe recombinant "vir4vac" RNA vaccines constitute a very safe and efficacious way of preventing serious infections of respiratory corona and paramyxoviruses as well as other respiratory viruses."

Background

More than a hundred teams worldwide are currently working on the development of a vaccine to prevent infection with SARS-CoV-2. Most of them follow with first-generation-candidates the **minimally acceptable profiles** for human vaccines according to the actual *Target Product Profile* (TPP) of WHO[1]: Those vaccines are applied only parenterally thus missing **induction of mucosal immunity in the respiratory tract.**

A ***preferred vaccine*** according to the WHO TTP[1] should not only protect the vaccinated person against heavy symptoms of the disease. Moreover, it has to **block viral transmission** from one person to the other. Now, with reports documenting only weak or transient immunity after infection with SARS-CoV-2, this might become **the only way to stop** the ongoing epidemic **and eradicate** the virus. Parenteral vaccines cannot achieve this goal. Our "**vir4vac**" approach belongs to a small group of 3-5 vaccine candidates in the *WHO landscape of COVID-19 candidate vaccines*[2] employing respiratory viral vectors, which copy the natural way of respiratory infections.

➲ **Those candidates can induce immunity also in the airways, a prerequisite for Sterilizing Immunity.**



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Technology

Scientists from the Max-Planck-Institute of Biochemistry in Martinsried have generated novel "Semi-live" vaccines based on a respiratory Sendai virus (the "vir4vac" platform), which are characterized by highest safety features ensured by a full replication deficiency. This unique RNA-vectored vaccine platform guarantees prevention of any uncontrolled spread, amplification, persistence and potential mutations of recombinant vaccines within vaccinated people, even suitable for (high-)risk groups like immuno-compromised persons, young children and the elderly.

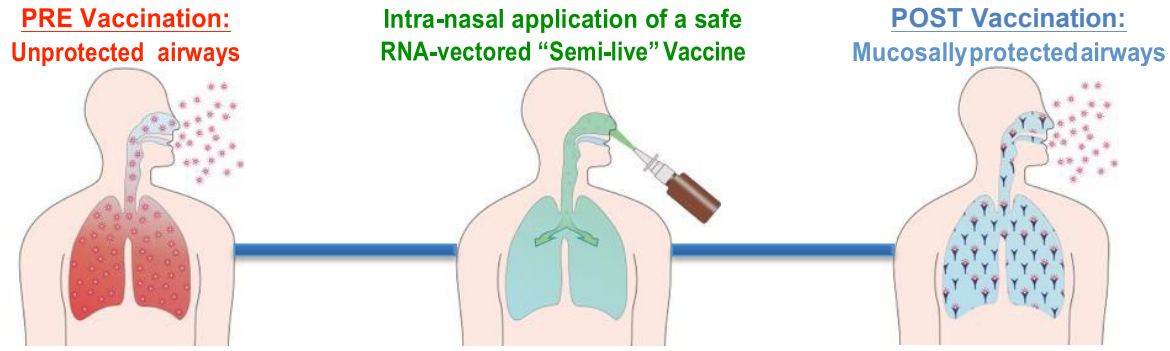
Most importantly, our RNA-vectored "Semi-live" vaccines mimic the natural viral infection process of all respiratory viruses characterized by an easy and ubiquitous distribution in all airways and efficient infection of the airway cells. Via simple intranasal application of our safe RNA-vectored vaccines protection directly in the airways is achieved by **mucosal** immunity**, a prerequisite for STERILIZING IMMUNITY**, followed by cellular and humoral immunity.

Further superior characteristics of these unique "SEMI-LIVE" Sendai virus vectors are

- Absence of any pre-existing anti-vector immunity or pre-immunity in humans - supporting vaccine efficacy,
- Simple non-traumatic mucosal administration (NO needles) - allows easy and widespread use,
- Scalable manufacturing due to our cell culture-based production platform (NO need for eggs or even live animals)

Current "vir4vac" projects:

- Proof of concept (PoC) of the "vir4vac" platform was demonstrated pre-clinically with a vaccine candidate encoding the RSV-F protein. Efficient mucosal (and systemic) antibody responses and **protection against challenge infections** have been achieved. This RSV vaccine candidate is now ready for a phase I clinical trial.
- Based on our well-characterized "vir4vac" vector platform, we designed comparable vaccine candidates against the actual pandemic SARS-CoV-2 virus. **SARS-CoV-2 S-gene candidates are ready for preclinical testing.**



Patent Information

- Initial basis patent (WO2006084746A1) covers the "vir4vac" technology very broadly.
- Worldwide protection of technology: granted in AU, AT, BE, CA, CN, CH, CZ, DE, DK, ES, FR, GB, IL, KR, MX, NL, SE, SK, EA/RU; pending in JP, US.
- A clearly defined patent strategy will allow new filings also in the future to extend the scope of protection.

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Selected Publications

1. WHO, Target Product Profile (TPP) SARS-CoV-2 Vaccine 09 April 2020; https://www.who.int/publications/m/item/who- target-product-profiles-for-covid-19-vaccines
2. WHO landscape of COVID-19 candidate vaccines 15 July 2020; https://www.who.int/publications/m/item/draft-landscape-of- covid-19-candidate-vaccines.
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).
4. 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).
5. 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.

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