Max-Planck-Innovation

Technology Offer

Max-Planck-Innovation GmbH

Amalienstr. 33
80799 Munich
Germany

Phone: +49 (89) 29 09 19 - 0
Fax: +49 (89) 29 09 19 -99
info@max-planck-innovation.de
www.max-planck-innovation.de

Contact:
Dr. Ingrid Kapser-Fischer
Tel.: 089 / 290919-19
kapser-fischer@max-planck-innovation.de

vir4vac

A completely new VACCINE inducing STERILIZING IMMUNITY against pandemic threats caused by viruses such as SARS-CoV-2 (COVID-19) or other respiratory pathogens

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Medical and Scientific Background of currently available vaccines against SARS-CoV-2

Currently licensed vaccines against SARS-CoV-2 (mRNA, vector type, etc.) all belong to the hastily developed 1st generation types of i.m. vaccines. At this time, according to the *Target Product Profile* (TPP) of the World Health Organization (WHO), these vaccines only deliver the **minimally acceptable profiles** for human vaccines.

Of note, all these vaccines have in common the disadvantage of a **weak or fully absent protection of the airways.**

In contrast, the **vir4vac** approach uses a unique respiratory viral vector, which fully copies the natural way of respiratory infections. In this line, the **vir4vac vaccine fully protects the airways** and thus fully breaks virus transmissions, thereby preventing any uncontrolled infections. Such vaccines are called **2nd generation vaccines**[1]**.**

Our **2nd generation vir4vac vaccine** already has proven **STERILIZING IMMUNITY** due to positive testing with the respiratory RSV virus. Our proven **induction of immunity in the airways** has great potential to stop the COVID-19 pandemia entirely; beyond that, **vir4vac's proprietary vaccine** addresses all upcoming new mutations**.**

The strictly intranasal route of vir4vac vaccine application as well as its storage at ambient temperatures further increase the acceptability of **vir4vac;** therefore, our novel **vir4vac vaccine** is optimally tailored to meet all challenges of world-wide mass vaccination programs such as storage, distribution, on-site application, etc.

Advantages of our 2nd generation vir4vac COVID-19 vaccine	Not available features in **1st generation vaccines** (*BioNTech, Moderna, AstraZeneca, J&J, Sputnik V*)
Provision of a **Profound Mucosal Immunity** in the airways ➔ SARS-CoV-2 no longer can be passed over from vaccinated to hitherto unvaccinated people. ➔ **STERILIZING IMMUNITY** ➔ **WORLD-WIDE ERADICATION** of SARS-CoV-2; thus, normal living is enabled to come back.	**Not available**
Simple needle-free intranasal application.	**Not available**
Stability allowing distribution at ambient temperatures.	**Not available** (only for J&J)

Technology

Scientists from the Max-Planck-Institute of Biochemistry have generated novel "Semi-live" vaccines (the "**vir4vac**" platform). Starting point was the respiratory Sendai virus, fully replication deficient, thus characterized by highest safety features[2,3].

This unique RNA-vectored vaccine platform guarantees the prevention of uncontrolled spread, shedding amplification, persistence and potential mutations/conversion of recombinant vaccines within vaccinated people, even suitable for (high-)risk groups like immuno-compromised persons, young children and the elderly.

This RNA-vectored "Semi-live" **vir4vac** vaccine mimics 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 vaccine (i) protection directly in the airways is reached by induction of a **profound anti-SARS-CoV-2 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).

Additional characteristics of the 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).

The "vir4vac" project

- Proof of concept (PoC) of the **vir4vac vaccine platform** was demonstrated pre-clinically with a vaccine candidate encoding the F protein of Respiratory Syncytial Virus (RSV). Efficient mucosal (and systemic) antibody responses and **protection against challenge infections** have been achieved[4]. This RSV vaccine candidate is now ready for a phase I clinical trial.
- Based on our well-characterized **vir4vac vaccine 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.**

This novel first-in-class intra-nasally applicable, recombinant RNA-Vectored **2nd generation vir4vac vaccine** constitutes a very safe and highly efficacious way of preventing serious infections **by completely blocking transmission** of agents that can be responsible for serious pandemics such as COVID-19.

We are now looking for either an investor and/or a licensing partner for this technology who is interested in the further clinical development of our state-of-the-art RNA-Vectored "Semi-live" vaccine platform.

We are willing to share detailed information and scientific data upon signing a CDA.

Listing by the WHO R&D Blueprint Team

2nd generation **vir4vac vaccine** is listed **on WHO´s** Draft landscape and tracker of COVID-19 candidate vaccines: https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines (category: Pre-Clinical).

Patent Information

- Initial basic patent (WO2006084746A1) covers the **vir4vac** technology very broadly.
- Worldwide protection of technology: granted in US, CN, D, F, GB, CH/LI.
- A clearly defined patent strategy will allow new filings also in the future to extend the scope of protection.

Selected Publications

1. WHO, Target Product Profile (TPP) SARS-CoV-2 Vaccines; https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines
2. 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).
3. 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.
4. 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).